

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS-1449-F]

RIN 0938-AR64

Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule

SUMMARY: This final rule updates the hospice payment rates and the wage index for fiscal year (FY) 2014, and continues the phase out of the wage index budget neutrality adjustment factor (BNAF). Including the FY 2014 15 percent BNAF reduction, the total 5 year cumulative BNAF reduction in FY 2014 will be 70 percent. The BNAF phase-out will continue with successive 15 percent reductions in FY 2015 and FY 2016. This final rule also clarifies how hospices are to report diagnoses on hospice claims, and provides updates to the public on hospice payment reform. Additionally, this final rule changes the requirements for the hospice quality reporting program by discontinuing currently reported measures and implementing a Hospice Item Set with seven National Quality Forum (NFQ) endorsed measures beginning July 1, 2014, as proposed. Finally, this final rule will implement the hospice Experience of Care Survey on January 1, 2015, as proposed.

EFFECTIVE DATE: These regulations are effective on October 1, 2013.

FOR FURTHER INFORMATION CONTACT:

Debra Dean-Whittaker, (410) 786 -0848, for questions regarding the hospice experience of care

survey.

Robin Dowell, (410) 786-0060, for questions regarding quality reporting for hospices and collection of information requirements.

Hillary Loeffler, (410) 786-0456, for general questions about hospice payment.

Katherine Lucas, (410) 786-7723 for questions regarding payment reform.

Anjana Patel, (410) 786-2120, for questions regarding the FY 2014 hospice wage index and payment rates.

Kelly Vontran, (410) 786-0332, for questions on diagnosis reporting on hospice claims.

SUPPLEMENTARY INFORMATION:

Wage Index Addenda: In the past, the wage index addenda referred to in the preamble of our proposed and final rules were available in the **Federal Register**. However, the wage index addenda of the annual proposed and final rules will no longer be available in the **Federal Register**. Instead, these addenda will be available only through the internet on the CMS Web site at: (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html.) Readers who experience any problems accessing any of the wage index addenda related to the hospice payment rules that are posted on the CMS Web site identified above should contact Anjana Patel at 410-786-2120.

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Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing

the acronyms used and their corresponding meanings in alphabetical order below:

APU Annual Payment Update

BBA Balanced Budget Act of 1997

BLS Bureau of Labor Statistics

BMI Body Mass Index

BNAF Budget Neutrality Adjustment Factor

CAD Coronary Artery Disease

CAHPS® Consumer Assessment of Healthcare Providers and Systems

CBSA Core-Based Statistical Area

CCW Chronic Conditions Warehouse

CFR Code of Federal Regulations

CHC Continuous Home Care

CMS Centers for Medicare & Medicaid Services

COPD Chronic Obstructive Pulmonary Disease

CoPs Conditions of Participation

CR Change Request

CVA Cerebrovascular Accident

CY Calendar Year

DME Durable Medical Equipment

FEHC Family Evaluation of Hospice Care

FR Federal Register

FY Fiscal Year

GAO Government Accountability Office

GIP General Inpatient Care

HCFA Healthcare Financing Administration

HHS Health and Human Services

HIS Hospice Item Set

HQRP Hospice Quality Reporting Program

ICD-9-CM International Classification of Diseases, Ninth Revision, Clinical Modification

ICD-10-CM International Classification of Diseases, Tenth Revision, Clinical Modification

IDG Interdisciplinary Group

IPPS Inpatient Prospective Payment System

IRC Inpatient Respite Care

LCD Local Coverage Determination

LUPA Low Utilization Payment Amount

MAP Measure Applications Partnership

MedPAC Medicare Payment Advisory Commission

MFP Multi-factor Productivity

MSA Metropolitan Statistical Area

NEC Not Elsewhere Classified

NF Long Term Care Nursing Facility

NPI National Provider Identifier

NQF National Quality Forum

OACT Office of the Actuary

OIG Office of Inspector General

OMB Office of Management and Budget

PEACE Prepare, Embrace, Attend, Communicate, and Empower

PRA Paperwork Reduction Act

PRRB Provider Reimbursement Review Board

QAPI Quality Assessment and Performance Improvement

RFA Regulatory Flexibility Act

RHC Routine Home Care

SBA Small Business Administration

SNF Skilled Nursing Facility

TEFRA Tax Equity and Fiscal Responsibility Act of 1982

TEP Technical Expert Panel

I. Executive Summary

A. Purpose

This final rule updates the payment rates for hospice providers for fiscal year (FY) 2014 as required under section 1814 (i) of the Social Security Act (the Act). The updates incorporate the use of updated hospital wage index data, the 5th year of the 7-year Budget Neutrality Adjustment Factor (BNAF) phase-out, and an update to the hospice payment rates by the hospice payment update percentage. Additionally, this final rule clarifies diagnosis reporting on hospice claims, provides an update on hospice payment reform and additional data collection requirements, and makes changes to the quality reporting requirements for hospice providers.

B. Summary of the Major Provisions

In this final rule we update the hospice payment rates for FY 2014 by 1.7 percent as described in section IV.C.3. We also update the FY 2014 hospice wage index with more current wage data, and the BNAF will be reduced by an additional 15 percent for a total BNAF reduction

of 70 percent as described in section IV.C.3. The August 6, 2009 FY 2010 Hospice Wage Index final rule (74 FR 39384) finalized a 10 percent reduced BNAF for FY 2010 as the first year of a 7-year phase-out of the BNAF, to be followed by an additional 15 percent per year reduction in the BNAF in each of the next 6 years. The total BNAF phase-out will be complete by FY 2016. This final rule also clarifies diagnosis reporting on hospice claims, especially regarding the use of non-specific symptom diagnoses; provides an update on hospice payment reform and additional data collection requirements; and finalizes a technical regulations text change. Additionally, this final rule changes the requirements for the hospice quality reporting program by discontinuing currently reported measures and implementing a Hospice Item Set with seven National Quality Forum (NQF) endorsed measures beginning July 1, 2014, as proposed. Finally, this final rule will implement the hospice Experience of Care Survey on January 1, 2015, as proposed.

C. Summary of Costs, Benefits, and Transfers

TABLE 1

Provision Description	Total	
FY 2014 Hospice Payment Rate Update	The overall economic impact of this final rule is an estimated \$160 million in increased payments to hospices.	
Costs for Hospices to Submit Data	The total cost to hospice providers, for submitting data to the Hospice Item Set starting in July 2014, is \$14.3 million.	

II. Background

A. Hospice Care

Coping with a life-limiting illness can be an overwhelming experience, physically, emotionally and spiritually, for both the person and his or her family. Recognition that the care needs at end-of-life are different from other health care needs is a foundation of the Medicare Hospice Benefit. Hospice is a compassionate care philosophy and practice for those who are terminally ill. It is a holistic approach to treatment that recognizes that the impending death of

an individual warrants a change from curative to palliative care. Palliative care means "patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice" (42 CFR 418.3). Palliative care is at the core of hospice philosophy and care practices. The person beginning hospice care, or his or her representative, needs to understand that his or her illness is no longer responding to medical interventions to cure or slow the progression of disease and then must choose to stop further curative attempts while palliative care continues and intensifies, as needed, for continued symptom management. As we stated in the June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32088), palliative care is an approach that "optimizes quality of life by anticipating, preventing, and treating suffering." The goal of palliative care in hospice is to improve the quality of life of individuals and their families facing the issues associated with life-threatening illness through the prevention and relief of suffering by means of early identification, assessment and treatment of pain and other issues. In addition, palliative care in hospice includes coordinating care services, reducing unnecessary diagnostics or ineffective therapies, and offering ongoing conversations with individuals and their families about changes in the disease and shifts in the plan of care to meet the changing needs with disease progression as the individual approaches the end-of-life.

Medicare hospice care is palliative care for individuals with a prognosis of living 6 months or less if the terminal illness runs its normal course. As generally accepted by the medical community, the term "terminal illness" refers to an advanced and progressively deteriorating illness, and the illness is diagnosed as incurable. When an individual is terminally ill, many health problems are brought on by underlying condition(s), as bodily systems are

interdependent. In the June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32088), we stated "the medical director must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness." As referenced in our regulations at 42 CFR 418.22(b)(1), to be eligible for Medicare hospice services, the beneficiary's attending physician (if any) and the hospice medical director must certify that the individual is terminally ill, that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course as defined in section 1861(dd)(3)(A) of the Act and our regulations at §418.3. The certification of terminal illness must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms as stated in §418.22(b)(3).

The goal of hospice care is to make the hospice patient as physically and emotionally comfortable as possible, with minimal disruption to normal activities, while remaining primarily in the home environment. Hospice care uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through the use of a broad spectrum of professional and other caregivers and volunteers. While the goal of hospice care is to allow for the individual to remain in his or her home environment, circumstances during the end-of-life may necessitate short-term inpatient admission to a hospital, skilled nursing facility (SNF), or hospice facility for procedures necessary for pain control or acute or chronic symptom management that cannot be managed in any other setting. These acute hospice care services are to ensure that any new or worsening symptoms are intensively addressed so that the individual can return to his or her home environment under routine hospice care. Short-term, intermittent,

inpatient respite services are also available to the family of the hospice patient when needed to relieve the family or other caregivers. Additionally, an individual can receive continuous home care during a period of crisis in which an individual requires primarily continuous nursing care to achieve palliation or management of acute medical symptoms so that the individual can remain at home. Continuous home care may be covered on a continuous basis for as much as 24 hours a day, and these periods must be predominantly nursing care per our regulations at §418.204. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care rate (§418.302(e)(4)).

B. History of the Medicare Hospice Benefit

Before the creation of the Medicare Hospice Benefit, hospice was originally run by volunteers who cared for the dying. During the early development stages of the Medicare Hospice Benefit, hospice advocates, working with legislators, were clear that they wanted a Medicare benefit available that provided all-inclusive care for terminally-ill individuals, provided pain relief and symptom management, and offered the opportunity to die with dignity in the comfort of one's home rather than in an institutional setting.

As stated in the August 22, 1983 proposed rule entitled "Medicare Program; Hospice Care" (48 FR 38146), "the hospice experience in the United States has placed emphasis on home care. It offers physician services, specialized nursing services, and other forms of care in the home to enable the terminally ill individual to remain at home in the company of family and friends as long as possible." The concept of a beneficiary "electing" the hospice benefit and being certified as terminally ill were two key components in the legislation responsible for the creation of the Medicare Hospice

¹ Connor, Stephen. (2007). Development of Hospice and Palliative Care in the United States. OMEGA. 56(1), p89-99.

Benefit (section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). (Pub. L. 97-248)). Section 122 of TEFRA created the Medicare Hospice Benefit, which was implemented on November 1, 1983. Under section 1861(dd) of the Social Security Act (the Act), codified at 42 U.S.C. 1395x(dd), we provide coverage of hospice care for terminally ill Medicare beneficiaries who elected to receive care from a Medicare-certified hospice. Our regulations at §418.54(c) stipulate that the comprehensive hospice assessment must identify the patient's physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions, and address those needs in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must take into consideration the following factors: the nature and condition causing admission (including the presence or lack of objective data and subjective complaints); complications and risk factors that affect care planning; functional status; imminence of death; and severity of symptoms. The Medicare Hospice Benefit requires the hospice to cover all reasonable and necessary palliative care related to the terminal prognosis and related conditions, as described in the patient's plan of care. The December 16, 1983 Hospice final rule (48 FR 56008) requires hospices to cover care for interventions to manage pain and symptoms. Clinically, related conditions are any physical or mental conditions that are related to or caused by either the terminal illness or the medications used to manage the terminal illness.² Additionally, the hospice Conditions of Participation at §418.56(b), hospice must provide all services necessary for the palliation and management of the terminal illness, related conditions and interventions to manage pain and symptoms. Therapy and interventions must be assessed and managed in terms of providing palliation and comfort

² Harder, PharmD, CGP, Julia. (2012). To Cover or Not To Cover: Guidelines for Covered Medications in Hospice Patients. The Clinician. 7(2), p1-3.

without undue symptom burden for the hospice patient or family.³ For example, a hospice patient with lung cancer (the terminal illness) may receive inhalants for shortness of breath (related to the terminal condition). The patient may also suffer from metastatic bone pain (a related condition) and would be treated with opioid analgesics. As a result of the opioid therapy, the patient may suffer from constipation (an associated symptom) and require a laxative for symptom relief. It is often not a single diagnosis that represents the terminal prognosis of the patient, but the combined effect of several conditions that makes the patient's condition terminal. We are restating what we communicated in the December 16, 1983 Hospice final rule (48 FR) 56010), regarding what is related versus unrelated to the terminal illness: "...we believe that the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case-by-case basis. It is our general view that hospices are required to provide virtually all the care that is needed by terminally ill patients." Therefore, unless there is clear evidence that a condition is unrelated to the terminal prognosis, all services would be considered related. It is also the responsibility of the hospice physician to document why a patient's medical needs would be unrelated to the terminal prognosis.

The fundamental premise upon which the hospice benefit was designed was the "revocation" of traditional curative care and the "election" of hospice care for end-of-life symptom management and maximization of quality of life, as stated in the December 16,1983 Hospice final rule (48 FR 56008). After electing hospice care, the patient typically returns to the home from an institutionalized setting or remains in the home, to be surrounded by family and friends, and to prepare emotionally and spiritually for death while receiving expert symptom

³ Paolini, DO, Charlotte. (2001). Symptoms Management at End of Life. JAOA. 101(10). p609-615.

management and other supportive services. Election of hospice care also includes waiving the right to Medicare payment for curative treatment for the terminal prognosis, and instead receiving palliative care to manage pain or symptoms.

The benefit was originally designed to cover hospice care for a finite period of time that roughly corresponded to a life expectancy of 6 months or less. Initially, beneficiaries could receive three election periods: two 90-day periods and one 30-day period. Currently, Medicare beneficiaries can elect hospice care for two 90-day periods and an unlimited number of subsequent 60-day periods; however, the expectation remains that beneficiaries have a life expectancy of 6 months or less if the terminal illness runs its normal course.

C. Services Covered by the Medicare Hospice Benefit

One requirement for coverage under the Medicare Hospice Benefit is that hospice services must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare certified hospice program. These covered services include: nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (now called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologics); medical appliances; counseling services (including dietary counseling); short-term inpatient care (including both respite care and procedures necessary for pain control and acute or chronic symptom management) in a hospital, nursing facility, or hospice inpatient facility; continuous home care during periods of crisis and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act.

Section 1814(a)(7)(B) of the Act requires that a written plan for providing hospice care to a beneficiary who is a hospice patient be established before care is provided by, or under arrangements made by, that hospice program and that the written plan be periodically reviewed by the beneficiary's attending physician (if any), the hospice medical director, and an interdisciplinary group (described in section 1861(dd)(2)(B) of the Act).

The services offered under the hospice benefit must be available, as needed, to beneficiaries 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act). Upon the implementation of the hospice benefit, the Congress expected hospices to continue to use volunteer services, though these services are not to be reimbursed (see Section 1861(dd)(2)(E) of the Act and 48 FR 38149). The hospice interdisciplinary group should be comprised of paid hospice employees as well as hospice volunteers, as stated in the August 22, 1983 Hospice proposed rule (48 FR 38149). This expectation is in line with the history of hospice and philosophy of holistic, comprehensive, compassionate, end-of-life care.

The National Hospice Study was initiated in 1980 through a grant sponsored by the Robert Wood Johnson and John A. Hartford Foundations and CMS (formerly, the Health Care Financing Administration (HCFA)). The study was conducted between October 1980 and March 1983. The study summarized the hospice care philosophy as the following:

- Patient and family know of the terminal condition.
- Further medical treatment and intervention are indicated only on a supportive basis.
- Pain control should be available to patients as needed to prevent rather than to just ameliorate pain.
- Interdisciplinary teamwork is essential in caring for patient and family.

• Family members and friends should be active in providing support during the death and bereavement process.

• Trained volunteers should provide additional support as needed.

In the August 22, 1983 Hospice proposed rule (48 FR 38149), we stated "the hospice benefit and the resulting Medicare reimbursement is not intended to diminish the voluntary spirit of hospices".

D. Medicare Payment for Hospice Care

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and our regulations in part 418, establish eligibility requirements, payment standards and procedures, define covered services, and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment in one of four prospectively-determined rate categories of hospice care (routine home care, continuous home care, inpatient respite care, and general inpatient care), based on each day a qualified Medicare beneficiary is under hospice care (once the individual has elected it). This per diem payment is to include all of the hospice services needed to manage the beneficiaries' care, as required by section 1861(dd)(1) of the Act. There has been little change in the hospice payment structure since the benefit's inception. The per diem rate based on level of care was established in 1983, and this payment structure remains today with some adjustments, as noted below:

1. Omnibus Budget Reconciliation Act of 1989

Section 6005(a) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L 101-239) amended section 1814(i)(1)(C) of the Act and provided for the following two changes in the methodology concerning updating the daily payment rates: (1) effective January 1, 1990, the

daily payment rates for routine home care and other services in included in hospice care were increased to equal 120 percent of the rates in effect on September 30, 1989; and (2) the daily payment rate for routine home care and other services included in hospice care for fiscal years beginning on or after October 1, 1990, were the payment rates in effect during the previous Federal fiscal year increased by the hospital market basket percentage increase.

2. Balanced Budget Act of 1997

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L 105-33) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were updated by a factor equal to the hospital market basket percentage increase, minus 1 percentage point. Payment rates for FYs from 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs will be the hospital market basket percentage increase for the FY. The Social Security Act requires us to use the inpatient hospital market basket to determine hospice payment rates.

3. FY 1998 Hospice Wage Index Final Rule

In the August 8, 1997 FY 1998 Hospice Wage Index final rule (62 FR 42860), we implemented a new methodology for calculating the hospice wage index based on the recommendations of a negotiated rulemaking committee. The original hospice wage index was based on 1981 Bureau of Labor Statistics hospital data and had not been updated since 1983. In 1994, because of disparity in wages from one geographical location to another, the Hospice Wage Index Negotiated Rulemaking Committee was formed to negotiate a new wage index methodology that could be accepted by the industry and the government. This Committee was comprised of representatives from national hospice associations; rural, urban, large and small

hospices, and multi-site hospices; consumer groups; and a government representative. The Committee decided that in updating the hospice wage index, aggregate Medicare payments to hospices would remain budget neutral to payments calculated using the 1983 wage index, to cushion the impact of using a new wage index methodology. To implement this policy, a BNAF would be computed and applied annually to the pre-floor, pre-reclassified hospital wage index when deriving the hospice wage index, subject to a wage index floor.

4. FY 2010 Hospice Wage Index Final Rule

Inpatient hospital pre-floor and pre-reclassified wage index values, as described in the August 8, 1997 Hospice Wage Index final rule are subject to either a budget neutrality adjustment or application of the wage index floor. Wage index values of 0.8 or greater are adjusted by the budget neutrality adjustment factor (BNAF). Starting in FY 2010, a 7-year phase-out of the BNAF began (August 6, 2009 FY 2010 Hospice Wage Index final rule (74 FR 39384), with a 10 percent reduction in FY 2010, and additional 15 percent reduction for a total of 25 percent in FY 2011, an additional 15 percent reduction for a total 40 percent in FY 2012, and an additional 15 percent reduction for a total of 55 percent in FY 2013. The phase-out will continue with an additional 15 percent reduction for a total reduction of 70 percent in FY 2014, an additional 15 percent reduction for a total reduction of 85 percent in FY 2015, and an additional 15 percent reduction for complete elimination in FY 2016. We note that the BNAF is an adjustment, which increases the hospice wage index value. Therefore, the BNAF reduction is a reduction in the amount of the BNAF increase applied to the hospice wage index value. It is not a reduction in the hospice wage index value, or in the hospice payment rates.

5. The Affordable Care Act

Starting with FY 2013 (and in subsequent FYs), the market basket percentage update

under the hospice payment system referenced in sections 1814(i)(1)(C)(ii)(VII) and 1814(i)(1)(C)(iii) of the Act will be annually reduced by changes in economy-wide productivity, as specified in section 1886(b)(3)(B)(xi)(II) of the Act, as amended by section 3132(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (the Affordable Care Act)). In FY 2013 through FY 2019, the market basket percentage update under the hospice payment system will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions as specified in section 1814(i)(1)(C)(v) of the Act).

In addition, sections 1814(i)(5)(A) through (C) of the Act, as amended by section 3132(a) of the Affordable Care Act, require hospices to begin submitting quality data, based on measures to be specified by the Secretary, for FY 2014 and subsequent fiscal years. Beginning in FY 2014, hospices which fail to report quality data will have their market basket update reduced by 2 percentage points.

Section 1814(a)(7)(D)(i) of the Act was amended by section 3132 (b)(2)(D)(i) of the Affordable Care Act, and requires, effective January 1, 2011, that a hospice physician or nurse practitioner have a face-to-face encounter with an individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification and attest that such visit took place. When implementing this provision, we decided that the 180th-day recertification and subsequent recertifications corresponded to the recertification for a beneficiary's third or subsequent benefit periods (August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47314)).

Further, section 1814(i)(6) of the Act, as amended by section 3132(a)(1)(B) of the Affordable Care Act, authorizes the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and other purposes. The types of data and information suggested in the Affordable Care Act would capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determines to be appropriate. The data collected may be used to revise the methodology for determining the payment rates for routine home care and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In addition, we are required to consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

6. FY 2012 Hospice Wage Index Final Rule

When the Medicare Hospice Benefit was implemented, the Congress included an aggregate cap on hospice payments, which limits the total aggregate payments any individual hospice provider can receive in a year. The Congress stipulated that a "cap amount" be computed each year. The cap amount was set at \$6,500 per beneficiary when first enacted in 1983 and is adjusted annually by the change in the medical care expenditure category of the consumer price index for urban consumers from March 1984 to March of the cap year (section 1814(i)(2)(B) of the Act). The cap year is defined as the period from November 1st to October 31st. As we stated in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314), for the 2012 cap year and subsequent cap years, the hospice aggregate cap will be calculated using the patient-by-patient proportional methodology, within certain limits. We will allow existing hospices the option of having their cap calculated via the original streamlined

methodology, also within certain limits. New hospices will have their cap determinations calculated using the patient-by-patient proportional methodology. The patient-by-patient proportional methodology and the streamlined methodology are two different methodologies for counting beneficiaries when calculating the hospice aggregate cap. A detailed explanation of these methods is found in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314). If a hospice's total Medicare reimbursement for the cap year exceeded the hospice aggregate cap, then the hospice would have to repay the excess back to Medicare.

E. Trends in Medicare Hospice Utilization

Since the implementation of the hospice benefit in 1983, and especially within the last decade, there has been substantial growth in hospice utilization. The number of Medicare beneficiaries receiving hospice services has grown from 513,000 in FY 2000 to over 1.3 million in FY 2012. Similarly, Medicare hospice expenditures have risen from \$2.9 billion in FY 2000 to \$14.7 billion in FY 2012. Our Office of the Actuary (OACT) projects that hospice expenditures are expected to continue to increase by approximately 8 percent annually, reflecting an increase in the number of Medicare beneficiaries, more beneficiary awareness of the Medicare Hospice Benefit for end-of-life care, and a growing preference for care provided in home and community-based settings. However, this increased spending is partly due to an increased average lifetime length of stay for beneficiaries, from 54 days in 2000 to 86 days in FY 2010, an increase of 59 percent.

There have also been noted changes in the diagnosis patterns among Medicare hospice enrollees, with a growing percentage of beneficiaries with non-cancer diagnoses. Specifically, there were notable increases between 2002 and 2007 in neurologically-based diagnoses, including various dementia diagnoses. Additionally, there have been significant increases in the

use of non-specific, symptom-classified diagnoses, such as "debility" and "adult failure to thrive." In FY 2012, both "debility" and "adult failure to thrive" were in the top five claims-reported hospice diagnoses and were the first and third most common hospice diagnoses, respectively (see Table 2 below).

Table 2: The Top Twenty Principal Hospice Diagnoses, FY 2002, FY 2007, FY 2012

Rank	ICD-9/Reported Principal Diagnosis		Total Patients	Percentage
		Year: 2002 Total Patients= 663,406		
1	162.9	Lung Cancer	73,769	11%
2	428.0	Congestive Heart Failure	45,951	7%
3	799.3	Debility Unspecified	36,999	6%
4	496	COPD	35,197	5%
5	331.0	Alzheimer's Disease	28,787	4%
6	436	CVA/Stroke	26,897	4%
7	185	Prostate Cancer	20,262	3%
8	783.7	Adult Failure To Thrive	18,304	3%
9	174.9	Breast Cancer	17,812	3%
10	290.0	Senile Dementia, Uncomp.	16,999	3%
11	153.0	Colon Cancer	16,379	2%
12	157.9	Pancreatic Cancer	15,427	2%
13	294.8	Organic Brain Synd Nec	10,394	2%
14	429.9	Heart Disease Unspecified	10,332	2%
15	154.0	Rectosigmoid Colon Cancer	8,956	1%
16	332.0	Parkinson's Disease	8,865	1%
17	586	Renal Failure Unspecified	8,764	1%
18	585	Chronic Renal Failure (End 2005)	8,599	1%
19	183.0	Ovarian Cancer	7,432	1%
20	188.9	Bladder Cancer	6,916	1%
	Year: 2007 Total Patients= 1,039,099			
1	799.3	Debility Unspecified	90,150	9%
2	162.9	Lung Cancer	86,954	8%
3	428.0	Congestive Heart Failure	77,836	7%
4	496	COPD	60,815	6%
5	783.7	Adult Failure To Thrive	58,303	6%
6	331.0	Alzheimer's Disease	58,200	6%
7	290.0	Senile Dementia Uncomp.	37,667	4%
8	436	CVA/Stroke	31,800	3%
9	429.9	Heart Disease Unspecified	22,170	2%
10	185	Prostate Cancer	22,086	2%
11	174.9	Breast Cancer	20,378	2%
12	157.9	Pancreas Unspecified	19,082	2%

13	153.9	Colon Cancer	19,080	2%
14	294.8	Organic Brain Syndrome NEC	17,697	2%
15	332.0	Parkinson's Disease	16,524	2%
16	294.10	Dementia In Other Diseases w/o Behav. Dist.	15,777	2%
17	586	Renal Failure Unspecified	12,188	1%
18	585.6	End Stage Renal Disease	11,196	1%
19	188.9	Bladder Cancer	8,806	1%
20	183.0	Ovarian Cancer	8,434	1%
		Year: 2012 Total Patients = 1,328,651		
1	799.3	Debility Unspecified	161,163	12%
2	162.9	Lung Cancer	89,636	7%
3	783.7	Adult Failure To Thrive	86,467	7%
4	428.0	Congestive Heart Failure	84,333	6%
5	496	COPD	74,786	6%
6	331.0	Alzheimer's Disease	64,199	5%
7	290.0	Senile Dementia, Uncomp.	56,234	4%
8	429.9	Heart Disease Unspecified	32,081	2%
9	436	CVA/Stroke	31,987	2%
10	294.10	Dementia In Other Diseases w/o Behavioral Dist.	27,417	2%
11	174.9	Breast Cancer	22,421	2%
12	153.9	Colon Cancer	22,197	2%
13	157.9	Pancreatic Cancer	22,007	2%
14	332.0	Parkinson's Disease	21,183	2%
15	185	Prostate Cancer	21,042	2%
16	294.8	Other Persistent Mental Disclassified elsewhere	17,762	1%
17	585. 6	End Stage Renal Disease	17,545	1%
18	518.81	Respiratory Failure	12,962	1%
19	294.11	Dementia In Other Diseases w/ Behavioral Dist.	11,751	1%
20	188.9	Bladder Cancer	10,511	1%

Source: FY 2002, 2007, and 2012 hospice claims data from the Chronic Conditions Warehouse (CCW), accessed on February 14 and February 20, 2013.

Note(s): The frequencies shown represent beneficiaries that had a least one claim with the specific ICD-9 code reported as the principal diagnosis. Beneficiaries could be represented multiple times in the results if they have multiple claims during that time period with different principal diagnoses.

III. Summary of the Provisions of the Proposed Rule

The May 10, 2013 FY 2014 hospice proposed rule (78 FR 27823) included the following clarifications, proposals, and updates:

- Diagnosis reporting on claims;
- Proposed update to the Hospice Quality Reporting Program;

- FY 2014 Rate Update;
- Update on Hospice Payment Reform and Data Collection; and
- Technical and Clarifying Regulations Text Change.

A. Diagnosis reporting on claims

The FY 2014 Hospice Wage Index and Payment Rate Update proposed rule clarified appropriate diagnosis reporting on hospice claims. No proposals were made regarding diagnosis coding. These clarifications are not to preclude any clinical judgment in determining a beneficiary's eligibility for hospice services. Eligibility for hospice services is based on meeting the eligibility requirements as stated in §418.20 of our regulations: "an individual must be—

- (a) Entitled to Part A of Medicare; and
- (b) Certified as being terminally ill in accordance with §418.22."

1. ICD-9-CM Coding Guidelines

The hospice benefit covers all care for the terminal illness, related conditions, and for the management of pain and symptoms. HIPAA, federal regulations, and the Medicare hospice claims processing manual all require that ICD-9-CM Coding Guidelines be applied to the coding and reporting of diagnoses on hospice claims. Regarding diagnosis reporting on hospice claims, we clarified in our July 27, 2012 FY 2013 Hospice Wage Index notice (77 FR 44247 through 44248) that all providers are required to code and report the principal diagnosis as well as all coexisting and additional diagnoses related to the terminal condition or related conditions to more fully describe the Medicare patients they are treating.

2. Use of Nonspecific Symptom Diagnoses

The proposed rule included additional diagnosis clarifications to address current

and ongoing diagnosis reporting patterns noted on hospice claims, more specifically the use of nonspecific, symptom diagnoses and certain dementia diagnoses. In the proposed rule, we clarified that the ICD-9-CM codes of "debility" and "adult failure to thrive" listed in the ICD-9-CM Coding Guidelines under the classification, "Symptoms, Signs, and Ill-defined Conditions", are not to be used as principal diagnoses when a related definitive diagnosis has been established or confirmed by the provider. Therefore, in the proposed rule, we clarified that "debility" and "adult failure to thrive" should not be used as principal hospice diagnoses on the hospice claim form. When reported as a principal diagnosis, these would be considered questionable encounters for hospice care, and the claim would be returned to the provider for a more definitive principal diagnosis. "Debility" and "adult failure to thrive" could be reported on the hospice claim as other, additional, or coexisting diagnoses. The principal diagnosis reported should be the condition determined by the certifying hospice physician(s) as the diagnosis most contributory to the terminal decline.

3. Use of "Mental, Behavioral and Neurodevelopmental Disorders" ICD-9-CM Codes

The proposed rule also clarified the ICD-9-CM Coding Guidelines for certain dementia codes that are reported on hospice claims. There are several, but not all, codes that fall under the classification, "Mental, Behavioral and Neurodevelopmental Disorders," that encompass multiple dementia diagnoses that are frequently reported principal hospice diagnoses on hospice claims, but are not appropriate principal diagnoses per ICD-9-CM Coding Guidelines.

4. Guidance on Coding of Principal and Other, Additional, and/or Co-Existing Diagnoses

In the proposed rule, we reiterated that diagnosis reporting on the hospice claims should include the appropriate selection of principal diagnoses as well as the other, additional and coexisting diagnoses related to the terminal illness. In the July 27, 2012 FY 2013 Hospice

Wage Index notice (77 FR 44247), we provided in-depth information regarding longstanding, existing ICD-9-CM Coding Guidelines. We also discussed related versus unrelated diagnosis reporting on claims and clarified that "all of a patient's coexisting or additional diagnoses" related to the terminal illness or related conditions should be reported on the hospice claim. Based on analysis of preliminary claims data from the first quarter of FY 2013 (October 1, 2012 through December 31, 2012), 72 percent of providers still only report one diagnosis on the hospice claim. This hospice diagnosis data is comparable to the hospice diagnosis data reported in the July 27, 2012 FY 2013 Hospice Wage Index notice (77 FR 44242), in which we stated that over 77 percent of the hospice claims reported only a principal diagnosis.

Information on a patient's related and unrelated diagnoses should already be included as part of the hospice comprehensive assessment and appropriate interventions for the palliation and management of the terminal illness and related conditions should be incorporated into the patient's plan of care, as determined by the hospice interdisciplinary group (IDG).

5. Transition to ICD-10-CM

The proposed rule reminded the hospice industry that ICD-10-CM will replace the ICD-9-CM on October 1, 2014. A critical issue associated with the transition to ICD-10-CM involves the matter of crosswalking between the ICD-9-CM and ICD-10-CM code sets. The term "crosswalking" is generally defined as the act of mapping or translating a code in one code set to a code or codes in another code set. (The terms "crosswalking" and "mapping" are sometimes used interchangeably.) Understanding crosswalking will be important to physicians during the transition phase when learning which new ICD-10 code to use in place of an ICD-9 code. We provided information regarding the crosswalks from ICD-9-CM to ICD-10-CM and this information is available for free and can be downloaded from the NCHS website,

www.cdc.gov/nchs/icd/icd10cm.htm. Hospices should not substitute crosswalking for learning and fully implementing ICD-10-CM into their procedures. Additional information regarding the transition to ICD-10-CM is available through the CMS website at:

http://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/icd10

B. Hospice Quality Reporting Program

- We proposed to eliminate two currently reported measures, the structural measure related to Quality Assurance and Performance Improvement (QAPI) and the NQF #0209 pain measure, and we offered an alternate proposal to retain the currently reported NQF #0209 pain measure until a suitable comfort outcome measure is available as described in section III.B.3 of the FY 2014 hospice wage index and payment update proposed rule (78 FR 27835);
- We proposed to implement the Hospice Item Set (HIS), a standardized patient-level data collection vehicle, effective 7/1/2014 and to utilize the seven NQF-endorsed measures derived from the HIS in the hospice quality reporting program as described in section III.B.4 of the FY 2014 hospice wage index and payment update proposed rule (78 FR 27836); and
- We proposed that hospices begin national implementation of the Hospice Experience of Care Survey by participating in a dry run in January 2015 through March 2015, and then, beginning in April 2015, conduct monthly implementation of the survey through December 2015 to meet the requirements of the 2017 annual payment update as described in section III.B.6 of the FY 2014 hospice wage index and payment update proposed rule (78 FR 27837).

C. FY 2014 Hospice Wage Index and Rates Update

The proposed updates to the hospice rates for FY 2014 are as follows:

• Update the hospice wage index using the 2013 pre-floor, pre-reclassified

hospital wage index as discussed in section III.C.1 of the FY 2014 hospice wage index and rate update proposed rule (78 FR 27839);

- Update the hospice wage index taking into account the application of the hospice floor or budget neutrality adjustment factor reduced an additional 15 percent, for a BNAF phase-out of 70 percent as finalized in the FY 2010 hospice wage index final rule (74 FR 39384), as discussed in section III.C.2 of the FY 2014 hospice wage index and rate update proposed rule (78 FR 27840); and
- Apply the hospice payment update percentage, as discussed in section III.C.3 of the FY 2014 hospice wage index and rate update proposed rule, to the FY 2013 hospice payment rates as discussed in section III.C.4 of the FY 2014 hospice wage index and rate update proposed rule (78 FR 27841 through 27842).

D. Update on Hospice Payment Reform and Data Collection

We did not make any payment reform proposals or solicit comments on this section, but included updates and a discussion of payment reform activities, including:

- A discussion of reform options, including the U-shaped curve model, a tiered model that uses the U-shaped curve, a short-stay add-on payment, and case-mix adjustment.
- A discussion of rebasing a portion of the routine home care (RHC) payment rate; adjusting for current costs would reduce the FY 2014 RHC rate by 10.1 percent.
- A discussion of the Office of Inspector General (OIG) and MedPAC recommendations to reduce payments to hospices for RHC patients in nursing facilities, to account for duplication of aide services. The claims visit data on aide services revealed that hospice patients in nursing facilities receiving more visits, but shorter visits than patients at

home; however, on average, hospice patients in nursing facilities receive 22 percent more minutes of aide care than hospice patients at home.

- A discussion of reform research findings related to cost reports and general inpatient care (GIP), and a link to the Abt Hospice Study Technical Report and an Abt review of the literature.
- A summary of comments received from a December, 2012 CMS website posting about additional data collection on hospice claims; a forthcoming Change Request will finalize the data collection this summer.
- An update on the status of the hospice cost report revisions, which were published as part of a Paperwork Reduction Act notice in the Federal Register on April 29, 2013.

E. Technical and Clarifying Regulations Text Change

We proposed a technical change to correct an erroneous cross reference in our regulations text at §418.311, as discussed in section III.E of the FY 2014 Hospice Wage Index and Rate Update proposed rule (78 FR 27847).

IV. Analysis and Responses to Public Comments

We received approximately 125 comments, many of which contained multiple comments, on the FY 2014 hospice wage index and payment rate update proposed rule. We received comments from various trade associations, private insurers, individual hospices, hospitals, physicians, medical directors, nurses, visiting nurses associations, home health agencies, hospice volunteers, and individuals. We appreciate the numerous thoughtful and insightful comments received and believe that communication and collaboration between CMS and all hospice stakeholders is imperative. The comments received and our responses to these comments are grouped by subject area and are summarized below.

A. Diagnosis Reporting on Hospice Claims

We made no new proposals regarding ICD-9-CM Coding Guidelines in the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule. However, we did make clarifications regarding ICD-9-CM Coding Guidelines for the selection of principal diagnoses and additional diagnoses. These clarifications are not to preclude any clinical judgment in determining a beneficiary's eligibility for hospice services. Eligibility for hospice services is based on meeting the eligibility requirements as stated in §418.20 of our regulations: "...an individual must be —

- (a) Entitled to Part A of Medicare; and
- (b) Certified as being terminally ill in accordance with §418.22." Specifically, we clarified the following:
- "Debility" or "adult failure to thrive" should not be used as a principal hospice diagnosis on the hospice claim form per ICD-9-CM Coding Guidelines. "Debility" and/or "adult failure to thrive" may be used as another, additional, or coexisting diagnosis on the hospice claim form. If "debility" or "adult failure to thrive" is reported as the principal diagnosis on the hospice claim forms, these claims will be returned to the provider for more definitive coding.
- Dementia codes classified under "Mental, Behavioral and Neurodevelopmental Disorders" are among the top twenty hospice claims reported diagnoses. Many of these codes are not appropriate as principal diagnoses because of manifestation/etiology guidelines or sequencing conventions under the ICD-9-CM Coding Guidelines. Particular attention must be paid to dementia diagnoses which are found under two separate ICD-9-CM classifications: "Mental, Behavioral, and Neurodevelopmental Disorders" and "Diseases of the Nervous System and Sense Organs." There are also dementia codes that are classified under "Diseases of the

Nervous System and Sense Organs" that also have sequencing conventions and, therefore, are not appropriate as principal diagnoses on the hospice claim.

- We provided ICD-9-CM coding guidance regarding the coding of principal and other, additional, and/or coexisting diagnoses. The principal diagnosis should reflect the condition to be chiefly responsible for the services provided. ICD-9-CM Coding Guidelines specify that the circumstances of an inpatient hospital admission diagnosis are to be used in determining the selection of a principal diagnosis. ICD-9-CM Coding Guidelines also state to "code all documented conditions at the time of the encounter/visit, and require or affect patient care treatment or management." The principal diagnosis reported on the hospice claim form should be determined by the hospice as the diagnosis most contributory to the terminal prognosis.
- Hospice providers are expected to report all coexisting or additional diagnoses
 related to the terminal illness and related conditions on the hospice claim to be in compliance
 with existing policy, and provide data needed for evaluating potential hospice payment reform
 methodologies.
- We reminded providers of the transition to ICD-10-CM, which will replace ICD-9-CM on October 1, 2014.
- Crosswalking from ICD-9-CM to ICD-10-CM is important for providers in understanding the transition between these two code sets.

We received 109 comments on diagnosis reporting on hospice claims, which are summarized below according to subsection.

1. ICD-9-CM Coding Guidelines

The hospice benefit covers all care for the terminal illness and related conditions,

including the management of pain and symptoms. HIPAA, federal regulations, and the Medicare hospice claims processing manual all require that ICD-9-CM Coding Guidelines be applied to the coding and reporting of diagnoses on hospice claims. Regarding diagnosis reporting on hospice claims, we clarified in our July 27, 2012 FY 2013 Hospice Wage Index notice (77 FR 44247 through 44248) that all providers should code and report the principal diagnosis as well as all coexisting and additional diagnoses related to the terminal condition or related conditions to more fully describe the Medicare patients they are treating.

<u>Comment</u>: Several commenters expressed concern that the coding clarification would require that hospices have a professional coder for coding claims, which would create a financial burden on hospice providers. Some commenters believed that we were asking hospices to hire professional coders. Other commenters thought that we were asking physicians to spend time determining the proper ICD-9-CM code for the claim.

Response: We did not state in the FY 2014 hospice wage index and payment update proposed rule that any hospice provider would be expected or required to have a professional coder to complete the coding on the hospice claims. Our discussion of the coding guidelines in the proposed rule was to assist hospice providers in complying with longstanding policies. In our regulations at 45 CFR 162.1002, the Secretary adopted the ICD-9-CM code set, including The Official ICD-9-CM Guidelines for Coding and Reporting. The CMS' Hospice Claims Processing Manual (Pub 100-04, chapter 11) requires that hospice claims include other diagnoses "as required by ICD-9-CM Coding Guidelines". In the proposed rule, we provided guidance from the ICD-9-CM Official Guidelines for Coding and Reporting to highlight coding guidelines for principal and other diagnosis selection, as well as the various coding and sequencing conventions found therein. This clarification of the coding guidelines was in response to the

monitoring of diagnostic reporting patterns noted on hospice claims, especially in regards to the reporting of only one diagnosis and the use of diagnoses not appropriate as principal diagnoses per the ICD-9-CM Coding Guidelines. We believe there are ample, available resources in regards to the ICD-9-CM Coding Guidelines to support hospice providers who choose not to have a professional coder complete their hospice claims, including the links provided within the proposed rule. These free resources are available at the following links:

http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/ICD 9ProviderDiagnosticCodes/, http://www.cms.gov/medicare-coverage-database/staticpages/icd-9-code-lookup.aspx , or on the CDC's website at:

http://www.cdc.gov/nchs/data/icd9/icd9cm_guidelines_2011.pdf

Additionally, more information regarding guidance for hospice claims coding can be found in the CMS' Hospice Claims Processing manual (Pub 100-04, chapter 11) available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c11.pdf. Finally, while hospice physicians use their clinical judgment to determine the principal diagnosis and related conditions, we do not require them to determine to the actual codes associated with those diagnoses for inclusion on the hospice claim. Hospices have the flexibility to determine how to take the physicians' information about diagnoses and translate it into the appropriate codes on the claim.

2. Use of Non-specific, Symptom Diagnoses

The proposed rule included additional diagnosis clarifications to address current and ongoing diagnosis reporting patterns noted on hospice claims, more specifically the use of nonspecific, symptom diagnoses and certain dementia diagnoses. In the proposed rule, we clarified that the ICD-9-CM codes of "debility" and "adult failure to thrive" are listed in the

ICD-9-CM Coding Guidelines under the classification, "Symptoms, Signs, and Ill-defined Conditions", and are not to be used as principal diagnoses when a related definitive diagnosis has been established or confirmed by the provider. Therefore, in the proposed rule, we clarified that "debility" and "adult failure to thrive" should not be used as principal hospice diagnoses on the hospice claim form. When reported as a principal diagnosis, these would be considered questionable encounters for hospice care, and the claim would be returned to the provider for a more definitive principal diagnosis. "Debility" and "adult failure to thrive" could be reported on the hospice claim as other, additional, or coexisting diagnoses. The principal diagnosis reported should be the condition determined by the certifying hospice physician(s) as the diagnosis most contributory to the terminal decline.

Comment: We received numerous comments in support of or acknowledging the need for these diagnostic clarifications and enforcement of existing coding guidelines. Several commenters acknowledged understanding the need to identify a principal hospice diagnosis when a patient has multiple diagnoses instead of using "debility" or "adult failure to thrive." Another commenter stated that their hospice program has tried to avoid the use of "debility" as a principal hospice diagnosis and agreed that this diagnosis has been over-used nationally; several commenters acknowledged that there has been "sloppy diagnosing" with the use of "debility" and "adult failure to thrive." One commenter stated that the use of "debility" or "adult failure to thrive" is most often a "failure to diagnose." One commenter stated that "debility" cannot be reported as a cause of the death on a death certificate in his state and that he had to select a different diagnosis for an immediate cause of death as well as a secondary, longer-term related cause. Several commenters asked what to expect regarding the application of the Local Coverage Determination (LCD) guidelines provided by the Home Health and Hospice Medicare

Administrative Contractors.

Response: We appreciate that some hospice providers are recognizing the issues regarding the inappropriate use of "debility" or "adult failure to thrive" as a principal hospice diagnosis reported on the hospice claim and are attempting to take steps to more fully describe their patient populations. We will continue to work with our Home Health and Hospice contractors to ensure that all LCDs will reflect these principal hospice diagnostic coding clarifications and that those eligible Medicare hospice beneficiaries will continue to have access to the benefits of hospice care. This collaboration will not be limited to the release of Change Requests, which can be found on our hospice website at

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-

<u>Transmittals.html</u>. Additionally, we encourage all interested stakeholders to participate in the CMS Home Health and Hospice Open Door Forums where questions, concerns and issues can be addressed with specialists within CMS. Information regarding Open Door Forums can be found on our website at http://www.cms.gov/Outreach-and-

Education/Outreach/OpenDoorForums/index.html.

Comment: There were a number of commenters who expressed concern that no longer allowing the use of "debility" or "adult failure to thrive" as a principal hospice diagnosis would limit or prohibit access to hospice care for Medicare beneficiaries. Commenters stated that by not allowing these two diagnoses to be coded as a principal hospice diagnosis, they believed that beneficiaries would elect hospice later in their disease trajectories. Other commenters felt that eligible beneficiaries would not be admitted to hospice care at all because a single definitive terminal diagnosis could not be determined by the certifying physician. Other commenters stated that it is difficult to determine a single principal terminal diagnosis for beneficiaries with

multiple chronic or coexisting conditions.

Response: Patient-centered care is at the core of the Medicare hospice benefit. Our mission is to be effective stewards of public funds, and we are committed to strengthening and modernizing the nation's health care system to provide access to high quality care. We believe that Medicare beneficiaries who are approaching end-of-life are at their most vulnerable state and should be afforded the most comprehensive and responsible clinical judgment. Medicare beneficiaries who are hospice eligible should be fully informed by their health care providers, including hospice providers, as to their conditions contributing to their terminal decline and their treatment options for ongoing care. We are aware that diagnosing diseases and determining prognosis is not always a perfect science. Certifying physicians should use their best clinical judgment in determining the principal diagnosis and related conditions, based on the hospice comprehensive assessment and review of any and all other clinical documentation.

It remains our belief that the goal of hospice care is to provide comprehensive, holistic, and individualized services to eligible Medicare beneficiaries. In order to receive these comprehensive hospice services, Medicare beneficiaries must be certified as terminally ill. This certification is based on the recommendation of the medical director in consultation with, or with input from, the beneficiary's attending physician (if any) and a comprehensive assessment of all body systems. The hospice regulations require that this certification be based on a variety of factors when making the clinical determination that a patient has a life expectancy of 6 months or less, should the illness run its normal course. The regulations in §418.25(b), Admission to hospice care, state, "In reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider at least the following information:

• Diagnosis of the terminal condition of the patient.

 Other health conditions, whether related or unrelated to the terminal condition.

• Current clinical relevant information supporting all diagnoses."

Based on this certification and the Medicare beneficiary's election of the hospice benefit, initial and ongoing comprehensive assessments are conducted to establish and maintain the hospice plan of care. A comprehensive hospice plan of care starts with accurate and thorough assessment and identification of the conditions (including diseases and symptoms) contributing to the terminal prognosis. This comprehensive plan of care is to include all the services and care needed for the management and palliation of the terminal illness and related conditions. This hospice plan of care is to include the following, per the Hospice Conditions of Participation:

- Interventions to manage pain and symptoms;
- A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs;
- Measurable outcomes anticipated from implementing and coordinating the plan of care;
 - Drugs and treatment necessary to meet the needs of the patient;
 - Medical supplies and appliances to meet the needs of the patient; and,
- The interdisciplinary group's documentation of the patient's or representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record (§418.56(c)).

A hallmark clinical characteristic of both "debility" and "adult failure to thrive" is the presence of multiple primary conditions. According to ICD 9 Coding Guidelines, codes that fall under the classification "Symptoms, Signs, and other Ill-defined Conditions", such as "debility"

and "adult failure to thrive", can only be used as a principal diagnosis when a related definitive diagnosis has not been established or confirmed by the provider. The individual diagnosed with "debility" or "adult failure to thrive" may have multiple comorbid conditions that individually, may not deem the individual to be terminally ill. However, the collective presence of these multiple comorbid conditions will contribute to the terminal prognosis of the individual.

Additionally, Medicare beneficiaries waive their right to Medicare payment for curative treatments under the Medicare Hospice Benefit; hospice providers are clinically and ethically responsible for ensuring that eligible Medicare beneficiaries are made fully aware of all of the conditions contributing to their terminal decline so they can make the informed decision as to which treatment approaches they would like to pursue.

As "debility" and "adult failure to thrive" are nonspecific, ill-defined, symptom diagnoses, they should not be reported as principal diagnosis. Rather, the condition that the hospice medical director determines is most contributory to the terminal prognosis should be reported as the principal diagnosis on the hospice claim and all other related conditions to the terminal prognosis should be reported as additional diagnoses. Therefore, the claim should include not only a principal diagnosis, but all other related diagnoses as well, to more fully describe the clinical picture of the terminally ill individual. In fact, reporting all of the related conditions that are contributing to the terminal prognosis on the hospice claim may also further support the eligibility for hospice services. Therefore, we do not believe that these coding clarifications will or should create any limitations or barriers to accessing Medicare hospice services by eligible Medicare beneficiaries, as coding on claims occurs after the beneficiary is fully informed and has chosen to elect and access hospice services. In fact, adherence to the ICD-9-CM Coding Guidelines should promote access to appropriate and comprehensive hospice

services. Medicare beneficiaries should always expect the right care at the right time and care that best suits their individual clinical status as well as their treatment preferences. Further, some medical experts have argued that these non-specific, ill-defined terms should be abandoned because they do not assist in the thoughtful evaluation of patients who may have treatable, underlying conditions⁴. We are clarifying these coding guidelines so that hospice providers can be more intentional about addressing all of the beneficiary's identified needs as he or she approaches end-of-life. One physician commenter stated that he reviews old records, calls attending physicians, and uses professional judgment to thoughtfully evaluate his patients for hospice care.

Analysis conducted by our hospice payment reform contractor, Abt Associates, of Medicare hospice beneficiaries with "debility" or "adult failure to thrive" reported as their principal hospice diagnosis, but no reported secondary diagnoses in FY 2012 revealed that over 50 percent of these hospice beneficiaries had seven or more chronic conditions and 75 percent had four or more chronic conditions as identified in the Chronic Condition Data Warehouse. The Chronic Condition Data Warehouse is a research database that includes Medicare, Medicaid assessments and Part D drug event data to support research designed to improve the quality of care and reduce cost and utilization. These chronic conditions include: Alzheimer's disease, non-Alzheimer's dementia, senile degeneration of the brain, congestive heart failure, chronic obstructive pulmonary disease, ischemic heart disease, chronic kidney disease, and various cancer diagnoses. While these conditions are labeled as chronic, many of these are often terminal conditions as well, while others are contributory to the terminal prognosis of the individual. See Table 3 below:

⁴ Pacala, J.T., Sullivan, G.M. eds. $Geriatrics\ Review\ Syllabus:\ A\ Core\ Curriculum\ in\ Geriatric\ Medicine.\ 7^{th}\ ed.\ New\ York:\ American\ Geriatrics\ Society;\ 2010.$

Table 3: Chronic Conditions of those Beneficiaries with "Debility" or "Adult Failure to Thrive" reported as Principal Hospice Diagnosis but with no Secondary Diagnoses Reported, FY 2012

Percent of Beneficiaries with Anemia	76%
Percent of Beneficiaries with Alzheimer's Disease and Related	66%
Disorders or Senile Dementia	
Percent of Beneficiaries with Rheumatoid Arthritis/Osteoarthritis	66%
Percent of Beneficiaries with Ischemic Heart Disease	63%
Percent of Beneficiaries with Depression	55%
Percent of Beneficiaries with Heart Failure	53%
Percent of Beneficiaries with Chronic Kidney Disease	43%
Percent of Beneficiaries with Chronic Obstructive Pulmonary Disease	39%
and Bronchiectasis	
Percent of Beneficiaries with Osteoporosis	39%
Percent of Beneficiaries with Alzheimer's Disease	38%
Percent of Beneficiaries with Stroke	34%
Percent of Beneficiaries with Atrial Fibrillation	28%
Percent of Beneficiaries with Hip/Pelvic Fracture	20%
Percent of Beneficiaries with Asthma	13%
Percent of Beneficiaries with Acute Myocardial Infarction	9%
Percent of Beneficiaries with Breast Cancer	7%
Percent of Beneficiaries with Prostate Cancer	5%
Percent of Beneficiaries with Colorectal Cancer	5%
Percent of Beneficiaries with Lung Cancer	2%
Percent of Beneficiaries with Endometrial Cancer	1%

Source: FY 2012 hospice claims data from Chronic Conditions Warehouse (CCW), accessed on June 27, 2013. N= 184,924 hospice beneficiaries with principal diagnosis of "debility" or "adult failure to thrive" with no reported secondary diagnoses on the hospice claim.

<u>Comment</u>: Several commenters stated that "Debility" is an allowable principal diagnosis under <u>ICD-9-CM Coding Guidelines</u> if there is no established or confirmed definitive diagnosis.

Response: While the ICD-9-CM Coding Guidelines state "codes that describe symptoms, signs, as opposed to diagnoses, are acceptable for reporting purposes when a related definitive diagnosis has not been established (confirmed) by the provider," we believe that in encompassing the true nature of the holistic hospice philosophy, these ill-defined diagnoses are not appropriate as the principal diagnosis on the hospice claim where an individual has typically had multiple health care encounters that have eventually led to their election of hospice services and physician certification as being terminally ill. In the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule (78 FR 27831), we clarified that if any or all of these

multiple primary conditions (as characterized under "debility" and "adult failure to thrive") have been or are being treated, or if medications have been prescribed for the patient to treat or manage any or all of these multiple primary conditions, we believe that these conditions meet the criteria of being established and/or confirmed by the beneficiary's health care provider and, thus, "debility" or "adult failure to thrive" would not be appropriate as the principal hospice diagnosis per ICD-9-CM Coding Guidelines. For those beneficiaries who have not had multiple health care encounters prior to hospice election, it is that much more important that certifying physicians make a thoughtful evaluation of all of the conditions contributing to an individual's terminal prognosis. The physician is responsible for making sure that the individual electing hospice care is fully aware of all treatment options available in order for that individual to make the most informed treatment decisions.

<u>Comment</u>: Several commenters noted that hospice eligibility is based on the prognosis and not the diagnosis, and some expressed concern as to why CMS is so focused on the diagnosis.

Response: To address the comments regarding the focus on diagnosis rather than prognosis, eligibility for hospice services under the Medicare Hospice Benefit has always been based on the prognosis of the individual, not diagnosis, since the implementation of the Medicare Hospice Benefit in 1983. As stated in the proposed rule on August 22, 1983, "The regulations would specify, consistent with the requirements of sections 1812 and 1814(a)(8) of the Act, that to be eligible for Medicare coverage of hospice care, an individual must be entitled to Medicare Part A, and must be certified as terminally ill" (48 FR 38147). These criteria have not changed, and we believe that all eligible individuals will continue to have access to the Medicare Hospice Benefit. However, certifications and recertifications of hospice eligibility are statutory

requirements for coverage and payment. The content of the certifications and recertifications must conform to the following requirements at §418.22(b), Content of certification. These requirements include, but are not limited to the following:

- The certification must specify that the individual's prognosis is for a life expectancy of six months or less if the terminal illness runs its normal course.
- Clinical information and other documentation that support the medical prognosis must be in the medical record with the written certification.
- The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms or as an addendum to these forms. On hospice claims however, we are not seeing the level of completeness of diagnosis reporting as is required for the certification and recertifications. As stated in the proposed rule, data analysis of preliminary hospice claims data from the first quarter of FY 2013 (October 1, 2012 through December 31, 2012) showed that over 72 percent of providers only report one diagnosis on the hospice claim. Further, analysis of third quarter FY 2013 data (April 1, 2013 through June 30, 2013 as of July 1, 2013) showed that 69 percent of providers still only report one diagnosis on the hospice claim. The hospice claims processing manual (IOM Publication #100- 04) states that principal and other diagnosis codes are to be reported on the hospice claims form per ICD-9-CM Coding Guidelines.

<u>Comment</u>: Some commenters felt that the only reason for the focus on diagnosis is for CMS to "save money" while shifting costs to the elderly and that the per diem reimbursement is being unbundled with these coding clarifications.

Response: The goal of any clarification of longstanding, existing policies such as those relating to ICD-9-CM Coding Guidelines is to more fully describe Medicare beneficiaries who

are receiving hospice care. We are also accountable for maintaining the integrity and fiscal viability of the Medicare Trust Funds. Diagnosis information on claims is also important as we move forward with hospice payment reform. Section 3132(a) of the Affordable Care Act for hospice payment reform requires that payment reforms occur no earlier than October 1, 2013, and that the revisions to the payments implemented result in the same estimated amount of aggregate expenditures for hospice care in the fiscal year that the revisions are implemented as would have been made for such care in such fiscal year if such revisions had not been implemented. That means any monies saved from any implemented reform model must go back into the hospice benefit. The goal of hospice payment reform is to ensure appropriate distribution of Medicare Trust Funds by better aligning payments with resource use, to pay more accurately.

However, there has been some concern, as noted by the Office of the Inspector General, that some hospices are not providing the full range of required hospice services, most notably drugs, through their per diem reimbursement to Medicare hospice beneficiaries (OIG Report A-06-10-00059, June, 2012). Data analysis conducted by our hospice payment reform contractor, Abt Associates, identified that some hospice-related drugs for Medicare hospice beneficiaries are being submitted through Part D prescription programs instead of being covered under the Medicare Hospice Benefit as required by the statute. In 2010, 773,168 Medicare hospice beneficiaries were enrolled in Part D. Of these individuals, almost 15 percent received over 334,000 analgesic prescriptions through Part D during hospice enrollment totaling \$13,000,430. See Figure (1) below.

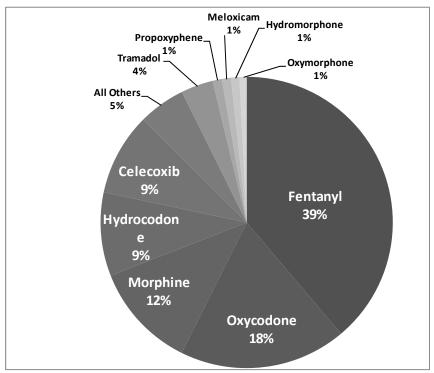


Figure (1): Analgesics Billed To Part D While Enrolled in Hospice

Source: FY 2010 Hospice beneficiaries matched with FY 2010 Part D claims from the Chronic Conditions Warehouse (CCW). Accessed on April 22, 2013.

This total covered only <u>one</u> drug class. During 2010, Medicare hospice beneficiaries received 5,878,425 prescriptions of all classes totaling \$351,750,202. These drug classes encompassed other hospice-related drugs including medications for nausea, shortness of breath, anxiety, constipation, diarrhea, depression, as well as disease-specific medications for the reported principal hospice diagnosis. We continue to conduct ongoing analysis regarding the claims for Medicare hospice beneficiaries to ensure that hospice providers are covering the required services, drugs, supplies, and DME as required by our regulations at 42 CFR 418.200, 418.202, and 418.204.

The hospice reimbursement structure has been a bundled per diem rate since the implementation of the Medicare Hospice Benefit. It is not our intent to "unbundle" any of the services required to be provided by hospices. However, as shown in the above figure, it is

evident that many drugs used for hospice pain management are being "unbundled" from the hospice per diem rate, and this is a concerning trend that we do not support.

Therefore, we continue to support the ICD-9-CM Coding Guidelines and stand by the ICD-9-CM coding clarifications in the proposed rule. These coding guidelines are longstanding policies that we have reiterated in past rules and notices. No new proposals are being made; rather we are ensuring that these existing policies are being adhered to. As such, "debility" and "adult failure to thrive" are not allowable as reportable principal diagnoses on the hospice claims. However, we recognize that this may be a paradigm shift for some hospices in the way they have coded in the past. Therefore, in recognizing the process and systems changes that need to be put in place, claims received with these codes in the principal diagnosis field will be returned to the provider for more definitive coding of the principal diagnosis and additional diagnoses, effective for claims dated on or after October 1, 2014. This will not affect claims submitted before October 1, 2014. "Debility" and "adult failure to thrive" may be reported on the hospice claims as additional diagnoses in the appropriate claim fields.

Although claims will not be returned to the provider until the start of FY 2015, we remind hospices that they are currently, and have always been, required to code <u>all</u> related diagnoses in the additional coding fields on the hospice claim and thus should be doing so now. We will continue to monitor and analyze hospice claims data and may make further clarifications in the future if necessary. In addition to the principal diagnosis field, the paper UC-04 claim form has up to 17 additional diagnosis fields and the electronic 837I 5010 claim form has up to 24 additional diagnosis fields allowing for adequate space for the coding all conditions related to the beneficiary's terminal prognosis.

Comment: Many comments were also received with specific clinical scenarios regarding

beneficiaries with a reported hospice diagnosis of "debility" or "adult failure to thrive." These comments went on to list these beneficiaries' comorbidities including COPD, atrial fibrillation, congestive heart failure, and stroke, to name a few. Other comments included clinical presentations, rather than specific diagnoses, and felt that "debility" or "adult failure to thrive" were the only appropriate diagnoses that could be assigned. These commenters also report that they were unable to determine the principal terminal diagnosis for these beneficiaries as the individual conditions did not meet criteria for being terminally ill per LCDs. Finally, additional commenters asked about quantifying comorbidities and whether Medicare guidelines for eligibility would be updated to support comorbidities as terminal diagnoses.

Response: As referenced in our regulations at §418.22(b)(1), to be eligible for Medicare hospice services, the beneficiary's attending physician (if any) and the hospice medical director must certify that the individual is terminally ill, that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course as defined in section 1861(dd)(3)(A) of the Act and set out at in §418.22. Therefore, eligibility under the Medicare Hospice Benefit is based on the prognosis of the individual and not only a single diagnosis or multiple diagnoses. As generally accepted by the medical community, the term "terminal illness" refers to an advanced and progressively deteriorating illness and the illness is diagnosed as incurable. When an individual is terminally ill, many health problems are brought on by underlying condition(s), as bodily systems are interdependent, meaning that there are multiple conditions, and hence diagnoses, contributing to the terminal prognosis. In the proposed rule, we said that the ICD-9-CM Coding Guidelines, referring to the selection of the principal diagnosis, state to list the diagnosis which is "chiefly responsible for the services provided and to list additional codes that describe any coexisting conditions." We clarified that the principal

diagnosis listed should be determined by the certifying hospice physician(s) as the diagnosis most contributory to the terminal prognosis. Furthermore, ICD-9-CM Coding Guidelines state that when there are two or more interrelated conditions (such as diseases in the same ICD-9-CM chapter or manifestations characteristically associated with a certain disease) potentially meeting the definition of principal diagnosis, either condition may be sequenced first, unless the circumstances of the admission, the therapy provided, the Tabular List, or the Alphabetic Index indicate otherwise. In the unusual instance when two or more diagnoses equally meet the criteria for principal diagnosis as determined by the circumstances of admission, diagnostic workup and/or therapy provided, and the Alphabetic Index, Tabular List, or other coding guidelines do not provide sequencing direction, any one of the diagnoses may be sequenced first. The ICD-9-CM Coding Guidelines are clear that all conditions contributing to the need for services should be listed.

One commenter provided the following clinical scenario regarding an individual with a hospice claims-reported principal diagnosis of "debility:"

"A patient has dilated cardiomyopathy and arrhythmia and has a functional classification of NYHA Class III as he has symptoms with activity but not at rest. He also has pulmonary fibrosis causing shortness of breath with activity. His PPS has declined to 50 percent in the last 3 months and he now needs to use a walker and the assistance for one person ambulating <10 ft. His weight has declined by 10 percent in the last six months, and he states that his appetite has decreased to eating breakfast and drinking two supplements during the day. He has been hospitalized two times in the past year for pneumonia and was hospitalized last month for arrhythmia requiring medication adjustments. He does not want further hospitalizations."

In this scenario, there are multiple conditions listed, including dilated cardiomyopathy, arrhythmia and pulmonary fibrosis. Though any of these conditions, individually, may not deem the individual as terminally ill, the progressive nature of these diseases as well as the collective presence of these multiple comorbid conditions will contribute to the terminal prognosis of the individual. We are clarifying that in a scenario such as this, the certifying physician would select the condition he or she feels is most contributory to the terminal prognosis, based on information in the comprehensive assessment, other relevant clinical information supporting all diagnoses, and his or her best clinical judgment. We are clarifying that this principal diagnosis, along with the other related diagnoses, would be included on the hospice claim. The physician's clinical judgment does not negate the fact that there must be a basis for hospice certification. A hospice needs to be certain that the physician's clinical judgment can be supported by clinical information and other documentation that provide a basis for the certification of a life expectancy of six months or less if the illness runs its normal course.

Additionally, the LCDs state that the terminal illness eligibility guidelines provided therein are applicable to all hospice patients regardless of diagnosis. The LCD guidelines are intended to be used to identify any Medicare beneficiary whose current clinical status and anticipated progression of disease is more likely than not to result in a life expectancy of six months or less. LCDs are utilized to determine eligibility for Medicare hospice services and not to determine the appropriate diagnoses to code on hospice claims.

The eligibility requirements for Medicare hospice services were stated above in a previous response. Eligibility under the Medicare Hospice Benefit is based on the prognosis of the individual and these criteria are not specific to or limited by any one condition, multiple conditions or presence of comorbidities. Rather, the certification of terminal illness is based in

the unique clinical picture of the individual that is reflected in the comprehensive assessment and other clinical records and documentation that deems the person as having a life expectancy of six months or less, should the illness run its normal course. Therefore, the Medicare Hospice Benefit eligibility requirements will not change as a result of the clarifications in the proposed rule. We believe that the certifying physicians have the best clinical experience, competence and judgment to make the determination that an individual is terminally ill. We continue to require the reporting of all related comorbidities, regardless of the quantity, in the hospice clinical record and on the hospice claims.

<u>Comment</u>: We received several comments regarding whether the reported principal diagnosis on the Certificate of Terminal Illness needs to be changed for current hospice beneficiaries where "debility" or "adult failure to thrive" was reported as the principal terminal condition.

Response: The regulations at §418.22(b) state that that the certification include--(1) The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course; (2) Clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section. Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment; (3) The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms, or as an addendum to the certification and recertification forms; (4) The physician or nurse practitioner who performs the face-to-face encounter with the patient described in paragraph §418.22 (a)(4) must attest in

writing that he or she had a face-to-face encounter with the patient, including the date of that visit. The attestation of the nurse practitioner or a non-certifying hospice physician shall state that the clinical findings of that visit were provided to the certifying physician for use in determining continued eligibility for hospice care; and (5) All certifications and recertifications must be signed and dated by the physician(s), and must include the benefit period dates to which the certification or recertification applies.

Certifications (of which the narrative is a part) are based on prognosis, not diagnosis as described above in the Code of Federal Regulations. Claims should include a principal diagnosis and all related diagnoses which form the prognosis. Certifications are completed no more than 15 days prior to the start of the benefit period. A new certification is not required simply because a beneficiary's principal diagnosis changes nor do benefit periods or election status change simply because a principal diagnosis changes.

Comment: We received some comments expressing concern that no longer allowing the use of "debility" and "adult failure to thrive" as principal hospice diagnoses would mean that Medicare hospice beneficiaries would be forced into a Medicare "cookie cutter" mold diagnosis. Several commenters stated that this would mean expensive diagnostic testing and/or hospitalizations to determine the terminal condition. Some commenters question what the expectations are for those people who are just "dying of old age" and some asked if CMS would rather see "otherwise healthy but elderly patients experience multiple hospital admissions and nursing home stays." Another commenter stated that doctors may feel compelled to "make-up" diagnoses to satisfy this coding clarification. One commenter asked if all codes under the classification of "Symptoms, Signs, and Ill-defined Conditions" are included in these clarifications.

Response: As stated above, these ICD-9-CM coding clarifications do not preclude the clinical judgment of the certifying physician(s) regarding the hospice eligibility of any given Medicare beneficiary; rather, they are to ensure that all principal and diagnoses related to the terminal prognosis are captured on the Medicare hospice claims to more accurately describe hospice beneficiaries receiving the services, drugs, supplies, and DME hospices are required to cover under the regulations at §418.200, §418.202, and §418.204. A non-specific, ill-defined symptom diagnosis such as "debility" and "adult failure to thrive" is more of a catch-all diagnosis in that a wide variety of principal and/or comorbid conditions contribute to these syndromes. Given the complexity of a hospice patient, with multiple conditions often contributing to the terminal prognosis, we are stating that all diagnoses contributing to (that is, related to) the terminal prognosis of the individual are to be reported on the hospice claims in order to account for the individual needs of each and every Medicare hospice beneficiary.

In evaluating an individual for hospice eligibility, and especially when evaluating an individual who has the clinical characteristics found under "debility" or "adult failure to thrive", "medical history is probably more important than physical examination or laboratory testing as failure to thrive commonly occurs over the course of months and common diagnostic testing has generally been done previously.⁵," Therefore, it is our belief that an individual who has elected hospice care and has been determined to be terminally ill by a certifying physician has more than likely already been assessed, treated and evaluated by health care providers, not limited to just hospice providers, prior to coming to the decision to elect hospice services and waive the right to Medicare payment for other curative services. Having all related conditions reported on the hospice claim form, and not just a single diagnosis, such as an ill-defined, symptom diagnosis,

⁵ Verdery, R. (1997). Clinical Evaluation of Failure to Thrive in Older People. Clinics in Geriatric Medicine. 13(4), 769-778.

will ensure that hospices are aware of and provide all of the expert care, including services, drugs, supplies, and DME, that a Medicare hospice beneficiary requires as he or she approaches end-of-life.

In the rare event that no single definitive terminal diagnosis (or diagnoses) can be determined by the certifying physician, whether from lack of clinical documentation or patient refusal for diagnostic work-up, then the expectation would be that all conditions that are present at the time of hospice certification that deem the individual as terminally ill would be reported on the hospice claim. One example provided by a commenter is as follows:

An 85 year old patient with dysphagia, decreased oral intake, malnutrition, weight loss, BMI of 18.6 upon admission, decreasing functional status, progressed from a walker to chair to bed in less than six months, but with no underlying diagnoses. This patient was determined to be terminally ill by the certifying physician and this patient was entered into hospice services.

In this example, while no organ-based diagnosis could be confirmed by the certifying physician, the clinical record reflects that this patient was suffering from malnutrition, dysphagia, and decreased functional status and muscle weakness.

Eligibility for hospice services is not limited by only disease-specific ICD-9-CM codes. There are ICD-9-CM codes for all of the clinical presentations listed above. This clinical scenario has been documented in the comprehensive assessment, and there is a clinical history of this patient's decline. CMS's expectation is to code these clinical presentations on the claim as they are listed in the clinical record. The condition the physician feels is most contributory to the terminal prognosis would be reported first on the hospice claim form, along with all other related conditions. There appears to be some confusion and disconnect from the comments received

regarding the coding expectations. The rationale for these clarifications is not to limit or prohibit access to hospice services, and we expect hospice providers to render the hospice care needed for those eligible individuals. We are only clarifying to code this level of specificity on the hospice claim form so we have an accurate clinical picture of those Medicare beneficiaries that are receiving hospice care under their Medicare Hospice Benefit. This expectation for specificity in claims coding is found in every other health care setting for Medicare beneficiaries—inpatient, outpatient, home health, skilled nursing facilities, acute rehabilitation facilities and in long term care hospitals. Hospices are expected to follow the same level of specificity especially given the complexity of the hospice patient population.

We recognize that this may be a great departure from the way some hospice providers have been accustomed to coding on hospice claims. Ongoing analysis of the hospice claims reveals that a majority of hospices are coding a single terminal diagnosis. However, eligibility should always have been based on the terminal prognosis of the patient, and this prognosis would typically involve more than one diagnosis. Specifically, as stated previously, analysis of third quarter FY 2013 data (April 1, 2013 through June 30, 2013 as of July 1, 2013) showed that 69 percent of providers still only report one diagnosis on the hospice claim. Prognosis, as many commenters have noted, is based on a multitude of clinical processes. We expect hospices to code these multiple clinical processes. This may be difficult for some providers to accept as they may not understand how malnutrition, anemia, or depression, for example, could be reported as a principal hospice diagnosis. However, many commenters provided clinical scenarios in which their patients had one or all of these clinical presentations that was contributing to the terminal prognosis of the individual. We expect hospice providers to take a holistic approach to diagnostic coding on the claims form, reporting the principal diagnosis and all related diagnoses.

According to §418.22(b)(3), Content of certification, "The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of six months or less as part of the certification and recertification forms; or as an addendum to the certification and recertification forms." Note that "clinical findings" are included in the determination of terminal prognosis, and hospice eligibility is not limited by or to a single diagnosis or diagnostic test result(s). Therefore, expensive diagnostic testing or hospitalizations are not a requirement for determining whether an individual meets Medicare hospice eligibility criteria if the individual's clinical circumstances are evident in that the conditions present contribute to the terminal prognosis of the individual. Oftentimes, if an individual has reported a past, resolved problem in their medical history, and that problem could cause the symptom syndromes of "debility" or "adult failure to thrive", that problem is the most likely one underlying the patient's presentation. The expectation remains that hospice providers, using their best clinical judgment, knowledge, and expertise, will "paint" a detailed picture of their patients to more fully describe Medicare hospice patients.

If a Medicare beneficiary is reported to be "dying of old age" or "otherwise healthy, but elderly," we believe that characterization of the beneficiary's condition is inconsistent with classifying the individual as terminally ill. Eligibility criteria for the Medicare Hospice Benefit do not include an age requirement, and advanced age alone is inadequate documentation of terminal prognosis.

It is normal clinical practice for health care providers to fully inform their patients about their health status. An eligible beneficiary who is considering hospice, and who has not seen a doctor in years, should be fully informed by the potential hospice provider about the conditions

⁶ Verdery, R. (1997). Clinical Evaluation of Failure to Thrive in Older People. Clinics in Geriatric Medicine. 13(4), 769-778.

contributing to their terminal prognosis and their palliative treatment options for ongoing care.

Often, many other treatable health conditions could be contributing to the clinical characteristics associated with "debility" and "adult failure to thrive." These conditions may include: Alzheimer's Disease, depression, primary anorexia, diabetes, cancer, chronic lung disease, stroke, chronic urinary tract infections, chronic steroid use, medication reactions, just to name a few. Any eligible individual (or representative) who is electing hospice under the Medicare Hospice Benefit must acknowledge that he or she has been given a full understanding of the palliative rather than the curative nature of hospice care, as it relates to the individual's terminal illness (§418.24(b)(2)). Upon electing the Medicare hospice benefit, an eligible patient acknowledges his/her understanding that Medicare will no longer pay for curative treatment for the terminal illness and related conditions, and thus the patient is essentially waiving curative treatment under Medicare, and instead elects to receive palliative care to manage pain or symptoms. It is the hospice provider's responsibility to ensure that the individual is fully informed and acknowledges understanding that he or she is essentially waiving curative treatment and electing only palliative care, so the individual (or representative) can make his or her own informed decision.

The expectation remains that all conditions (hence, diagnoses) that are contributing to (that is, related to) the terminal prognosis of the individual would be reported on the hospice claims to fully represent the individual's clinical status and the hospice interventions that are being provided to address the individual's needs.

We do not endorse "making up" a diagnosis in order for hospice claims submission. We believe that beneficiaries' physicians are in the best clinical position to determine those

⁷ Verdery, R. (1997). Clinical Evaluation of Failure to Thrive in Older People. Clinics in Geriatric Medicine. 13 (4), 769-778.

conditions that are contributing to the terminal prognosis of their patients. We expect that they will use responsible decision making to determine the diagnosis contributing most to the terminal prognosis utilizing the information from the clinical records and the comprehensive assessments. While the ICD-9-CM Coding Guidelines for "Symptoms, Signs and Ill-defined Conditions" do apply for all codes under this ICD-9-CM classification, we are currently focusing on the two most frequently reported hospice claims diagnoses from this classification, "debility" and "adult failure to thrive." However, we will continue to monitor the diagnostic coding patterns on hospice claims for any further issues or clarifications that may be needed in this regard.

<u>Comment</u>: A few commenters suggested, for those cases reported with "debility" or "adult failure to thrive" as the principal diagnosis, there should be a mandatory medical review rather than these patients not receiving hospice care or to only "punish" those that have abused "debility." One commenter suggested that CMS limit the number of patients per hospice with "debility" and "adult failure to thrive" with a 3 percent cap.

Response: As noted previously, "debility" and "failure to thrive" comprised 20 percent of the Medicare hospice population in FY 2012. This is a substantial number of individuals that hospice providers are saying have no other diagnoses or conditions that could be determined or confirmed. Conducting mandatory medical reviews on each and every one of these cases would require substantial administrative burden and costs. Rather, we are not stating that individuals with the clinical manifestations of "debility" and "adult failure to thrive" are ineligible for hospice services under the Medicare Hospice Benefit. Eligibility is determined by the certifying physician and based on the review of the clinical records and comprehensive assessment. These clarifications are to ensure that hospice providers are fully describing their Medicare hospice patients, which should assist them in fully understanding and treating all of the conditions

contributing to the terminal prognosis and not just a single terminal diagnosis.

It is our belief that hospice providers would not support having another cap requirement regarding their census populations. We recognize there are many new and ongoing requirements that hospice providers must fulfill in addition to providing high-quality, end-of-life care for Medicare beneficiaries. Therefore, it is not our intent, at this time, to implement any new cap requirements or "punishments" on hospice providers with these coding clarifications. We expect that hospice providers will continue to assess and evaluate their own organizational policies and processes to ensure that they are able to meet requirements and to continue to meet the needs of their patients.

Comment: One commenter stated, "The need to document secondary diagnoses is recognized. It was actually commonly done in the pre-electronic record (EMR) days, but got lost by many hospices with limitations in software systems". One commenter stated that barriers existed with electronic medical record systems that did not allow additional diagnoses to flow to the claim. These commenters went on to say that many of these barriers have been removed and that the majority of hospice providers are either now in compliance with the requirement to include multiple diagnoses or are in the process of implementing procedures and technology in order to be in compliance. One commenter stated that their hospice software vendor has not developed a process to allow for inclusion of related diagnoses on their claims forms. This commenter went on further to say that it would be an obstacle for hospice providers to make software changes to comply with the ICD-9-CM coding clarifications regarding the reporting of related diagnoses. Several commenters stated that the occurrence of reporting a principal diagnosis of "debility" or "adult failure to thrive" is uncommon.

Response: We appreciate the comment regarding the common hospice practice of

including secondary diagnoses in the past. While we understand that software systems may pose some obstacles in reporting more than one diagnosis on the hospice claim, we also believe that this practice of reporting the conditions contributing to (that is, related to) the terminal prognosis is one that has been communicated since the implementation of the hospice benefit. The expectation is for this practice to continue and for hospice providers to be active in ensuring that their processes and systems promote the hospice philosophy of holistic, comprehensive care and the intent of the Medicare Hospice Benefit in supporting that access for the Medicare population.

As mentioned in the proposed rule, there are hospice providers who are reporting more than just the principal diagnosis, so it appears that there are electronic systems currently in place that allow for the inclusion of multiple diagnoses. However, data analysis of hospice claims continues to show that the majority of hospice providers (69 percent of hospice providers, as stated in previous responses) continue to report only one diagnosis on hospice claims. Additionally, software systems are typically designed with end user input so we believe those software systems that only allow one diagnosis were because those hospices communicated to the software vendors that their needs for claims coding were to include only one diagnosis. We expect hospices to articulate to the vendors the requirements of the software that complies with our requirements. Furthermore, we have reiterated in past notices and rules regarding our expectation of the inclusion of the principal hospice diagnosis as well as all related conditions. As mentioned previously, in addition to the principal diagnosis field, the paper UC-04 claim form has up to 17 additional diagnosis fields, and the electronic 837I 5010 claim form has up to 24 additional diagnosis fields allowing for adequate space for the coding all conditions contributing to (that is, related to) the beneficiary's terminal condition. Therefore, we believe that we have provided ample notice and time for hospice providers to evaluate their claims

software systems to make the necessary systems adjustments for the inclusion of all related diagnoses. However, we also recognize that this will require some software systems adjustments for several hospice providers, and we are sensitive to those time requirement needs. To address the comments regarding the rare occurrences of the use of "debility" or "adult failure to thrive" as a principal diagnosis, a review of 2011 and 2012 data from the Chronic Condition Warehouse revealed the following information (See Table 4 and Table 5):

Table 4: Percentage of Hospice Providers Ever Reporting "Debility" or "Adult Failure to Thrive" as the Principal Hospice Diagnosis With No Reported Secondary Diagnose

Condition	FY 2011	FY 2012
Debility	89.3%	88.9%
Adult Failure to Thrive	87.3%	87.6%

Source: FY 2011 and FY 2012 Claims from Chronic Conditions Warehouse (CCW). Accessed on 7/19/13.

Table 5: Percentage of Claims with "Debility" or "Adult Failure to Thrive" as Reported Principal Diagnosis With No Reported Secondary Diagnoses

Condition	FY 2011	FY 2012
Debility	11.96%	12.07%
Adult Failure to Thrive	7.55%	7.83%

Source: FY 2011 and FY 2012 Claims data from Chronic Conditions Warehouse (CCW). Accessed on 7/19/13.

This data indicates that the majority of hospice providers are reporting "debility" and "adult failure to thrive" as a principal hospice diagnosis, thus this is not a rare occurrence as commenters have stated. Additionally, claims with "debility" or "adult failure to thrive" as the reported principal hospice diagnosis accounted for almost 20 percent of total hospice claims for both FY 2011 and FY 2012.

<u>Comment</u>: We received several comments regarding hospice claims with a principal diagnosis of "debility" or "adult failure to thrive" being returned to the provider immediately for

more definitive coding. Some expressed that CMS is "jumping the gun" by announcing that claims would be returned to the provider before the comment period is over and were concerned that claims would starting returning upon publication of the proposed rule. Several commenters expressed concern regarding the "denial of claims payment" for claims received with "debility" or "adult failure to thrive" reported as the principal diagnosis.

Response: We apologize for any confusion that may have resulted from our statement in the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule regarding claims being returned to providers for more definitive coding. We stated in the proposed rule: "...we would clarify that "debility" and "adult failure to thrive" would not be used as principal diagnoses of the hospice claim form. When reported as a principal diagnosis, these would be considered questionable encounters for hospice care, and the claims would be returned to the provider, not denied, for a more definitive principal diagnosis." We did not specify any time frame for these claims or the effective date of implementation. The intent was not to immediately return claims to the provider upon publication of the proposed rule, and the returned claim is not a denial of the claim, but a request for a more definitive and appropriate principal diagnosis. "Debility" and "adult failure to thrive" could be reported on the hospice claim as other, additional, or coexisting diagnoses. We understand that this is a shift from the way some hospice providers have coded in the past and that there needs to be adequate time to ensure that all clinical and electronic processes are in place and functioning as not to create unnecessary administrative burden in an accelerated time frame.

<u>Comment</u>: There were several comments questioning what is considered related or unrelated to the terminal condition. One commenter stated that it is difficult to determine if a diagnosis is related to the terminal condition with an example given stating that renal failure may

or may not be related to congestive heart failure. Another commenter, a hospice physician, provided a clinical scenario for a beneficiary with chronic obstructive pulmonary disease (COPD) as the principal diagnosis, but who also had coronary artery disease (CAD) and Parkinson's disease which the hospice considered unrelated comorbid conditions. The patient would only receive hospice services for care related to the lung disease (COPD). Another commenter expressed concern that including all of the related diagnoses on the hospice claim would mean that hospices would have additional costs incurred in covering all of the medications for the reported diagnoses.

Response: It is our goal to maintain the integrity of hospice philosophy and the Medicare Hospice Benefit. The intent of the Medicare Hospice Benefit is to provide all-inclusive care for pain relief and symptom management for the terminal prognosis and related conditions, and offer the opportunity to die with dignity in the comfort of one's home rather than in an institutional setting. It is often not a single diagnosis that represents the terminal prognosis of the patient, but the combined effect of several conditions that makes the patient's prognosis terminal. In §418.54(c), the hospice Conditions of Participation stipulate that the comprehensive hospice assessment must identify the patient's physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions which must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must take into consideration the following factors: the nature and condition causing admission (including the presence or lack of objective data and subjective complaints); complications and risk factors that affect care planning; functional status; imminence of death; and severity of symptoms (§418.54 (c)). The Medicare Hospice Benefit requires the hospice to cover all palliative care related to the terminal illness and related

conditions. The hospice plan of care is established based on the review of the clinical records and the comprehensive hospice assessments in order to ensure that all care needs at the end-of-life are addressed. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare certified hospice program. These covered services include: nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (now called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologics); medical appliances; counseling services (including dietary counseling); short-term inpatient care (including both respite care and procedures necessary for pain control and acute or chronic symptom management) in a hospital, nursing facility, or hospice inpatient facility; continuous home care during periods of crisis and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act.

We recognize that there are conditions that are unrelated to the terminal condition of the individual. This is why there are the ongoing assessment requirements of the hospice beneficiaries and the collaboration with the hospice IDG—to ensure that the ongoing and changing needs of the hospice beneficiary are assessed and changes to the plan of care are made. However, in referring to the holistic intent of hospice philosophy and care, we wrote in the August 22, 1983 proposed rule, "... we recognize that there are many illnesses which may occur when an individual is terminally ill which are brought on by the underlying condition of the patient" (48 FR 38147). In reviewing the many clinical scenarios provided by commenters and their interpretations of what they consider related versus unrelated, it is apparent that the majority refer to a "related condition" as one that is related only to the reported single, principal

terminal diagnosis and not to the terminal prognosis. However, within those same comments, it was stated numerous times that hospice eligibility is related to the prognosis of the individual. One example provided from a hospice physician regarding a Medicare hospice beneficiary who had a reported principal terminal diagnosis of chronic obstructive pulmonary disease (COPD). This individual also had documented coronary artery disease (CAD) and Parkinson's disease. The provider stated that the CAD and the Parkinson's disease are unrelated to the COPD and that the patient would only receive hospice services for the COPD. This scenario and accompanying statement does not appear to encompass hospice philosophy of holistic care. Therefore, we are restating what we communicated in the December 16, 1983 Hospice final rule regarding what is related versus unrelated to the terminal illness: "...[W]e believe that the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case-by-case basis. As stated in the December 16, 1983 Hospice final rule, ... "hospices are required to provide virtually all the care that is needed by terminally ill patients." (48 FR 56010). Therefore, unless there is clear evidence that a condition is unrelated to the terminal prognosis, all services would be considered related. It is also the responsibility of the hospice physician to document why a patient's medical need(s) would be unrelated to the terminal prognosis. We continue to reiterate that this determination of what is related versus unrelated to the terminal prognosis remains within the clinical expertise and judgment of the hospice medical director in collaboration with the IDG.

<u>Comment</u>: Two commenters stated that the reference to the 1983 final rule preamble language quoted above, is casting aside language found in the §418.402, "Individual liability for services that are not covered hospice care". These comments went on to say that §418.402 "identified items as unrelated and not the responsibility of the hospice for 'services received for

the treatment of an illness or injury not related to the individual's terminal condition'."

Response: The referenced §418.402, "Individual liability for services that are not considered hospice care" states, "Medicare payment to the hospice discharges an individual's liability for payment for all services, other than the hospice coinsurance amounts described in §418.400..." This section goes on to state what payment liabilities a hospice beneficiary would be responsible for (not the hospice provider per the commenters) including "...Medicare deductibles and coinsurance payments and for the difference between the reasonable and actual charge on unassigned claims on other covered services that are not considered hospice care." Examples of non-hospice services are provided in this section including "...Medicare services received for the treatment of an illness or injury not related to the individual's terminal condition." We have previously acknowledged that there are those rare circumstances in which a service may not be related to the patient's terminal prognosis and that this determination is to be done on a case-by-case basis by the hospice physician with input from the IDG. However, §418.402 refers to the liability limitations for the hospice beneficiary and does not refer to the liability to the hospice provider. To infer that this section is a confirmation of the liability limitations to the hospice provider would be incorrect.

Comment: Several commenters stated that the hospice physician, along with input from the IDG, have a process in place to help determine related versus unrelated conditions and results in the holistic and comprehensive care their patients need. Other commenters explained that the software system utilized by their hospice agency marks conditions either as "active" (meaning, related) or "historical" (meaning, unrelated). If a condition went from a historical state to an active state during the course of a hospice episode, then that condition was then considered related and treated accordingly under the hospice plan of care. Another commenter said that

while some conditions are unrelated to the terminal condition, the clinical manifestations of these unrelated conditions are as such that they contribute to the individual's symptom burden, and the hospice provider still provides symptom management for these seemingly unrelated conditions to meet the patient's needs.

Response: We applaud these hospices in providing a patient-centered approach and embracing the holistic hospice philosophy. These are all examples of hospice providers coming up with innovative ways to manage the needs of the hospice beneficiaries. These are reflections of the true intent of hospice philosophy that have been incorporated into the Medicare Hospice Benefit. We encourage all hospice providers to assess their operational processes and clinical and claims systems to be innovative in meeting the challenges of providing end-of-life care for the Medicare hospice beneficiaries as health care, in general, transitions to accountability and value-based models of care.

<u>Comment</u>: One commenter stated that these diagnostic clarifications are a change in coverage policy and CMS must use a National Coverage Decision process to change coverage policy rather than through the preamble discussion of the proposed rule.

Response: We continue to state that these coding clarifications are for hospice claims reporting only and are not a question of hospice eligibility or access to coverage. Eligibility to access the Medicare Hospice Benefit remains the same since the implementation of the benefit in 1983. To restate, eligibility for the Medicare Hospice Benefit is based on the individual being entitled to Part A of Medicare and being certified as terminally ill in accordance with §418.22. These eligibility requirements for coverage have not changed and are not changing in this rule. We expect hospice providers will not discharge, from hospice services, those beneficiaries who meet eligibility requirements but for whom they cannot determine a single, principal hospice

diagnosis. If a Medicare beneficiary meets the eligibility requirements as stated in §418.20 and as referenced above, that Medicare beneficiary will have access to hospice services under the Medicare Hospice Benefit. The intent of these coding clarifications is to request more clarity and detail on the hospice claims to reflect a complete picture of the Medicare hospice population and the hospice services rendered and not to make any changes in coverage or eligibility policies. Therefore, we reject the comment that CMS must use the National Coverage Decision process.

Comment: We received a few suggestions to help further clarification regarding diagnostic coding in the hospice setting. One commenter suggested that CMS work with the National Hospice and Palliative Care Organization (NHPCO) to develop guidelines regarding diagnostic coding for hospices. Another commenter suggested that CMS needs to guide standardization of the hospice industry. The American Academy of Hospice and Palliative Medicine (AAHPM) suggested collaboration with CMS to convene a Palliative Medicine and Hospice Coding and Documentation Learning Network to have ongoing dialogue regarding coding issues and suggestions for the hospice industry.

Response: We appreciate the numerous thoughtful and insightful suggestions that have been provided in response to the diagnostic clarifications. CMS strives to involve all stakeholders in the collaborative process as health care navigates through the 21st century and health care reform provisions. We continue to have ongoing discussions with the industry, including the national hospice organizations, to remain aware of the issues that affect the hospice providers and impact Medicare beneficiaries. We believe that this communication and collaboration will reflect in our ongoing advocacy for the Medicare hospice beneficiaries to ensure accountability, responsibility and quality end-of-life care. We will continue to provide outcomes of these communications via Medicare Learning Network (MLN) articles and through

our Open Door Forums to ensure that all Medicare stakeholders are kept informed of progress in maintaining the integrity of the Medicare Hospice Benefit.

Final Decision: We will require these coding changes beginning on October 1, 2014. On or after October 1, 2014, any claims with "debility" or "adult failure to thrive" in the principal diagnosis field will be returned to the provider for more definitive principal diagnosis coding. Claims submitted prior to October 1, 2014 with "debility" or "adult failure to thrive" in the principle diagnosis field on the claim will not be returned to the provider, but we expect that hospice providers will code the principal hospice diagnosis according to the ICD-9-CM Coding Guidelines and the clarifications made herein. This should provide more than ample time for hospice providers to meet with clinical staff and their software vendors to ensure that these coding needs are addressed and processes put into place to ensure continuity of care and systems. These returned claims, based on the principal diagnoses of "debility" or "adult failure to thrive," are not a denial of payment because of questionable eligibility; rather, these claims are being returned for additional clarity. Once resubmitted with diagnostic codes following the ICD-10-CM Coding Guidelines, these claims will be processed and paid accordingly. However, we expect hospice providers to transition immediately to more thoughtful coding practices in advance of this effective date.

3. Use of "Mental, Behavioral and Neurodevelopmental Disorders" ICD-9-CM Codes
In the proposed rule we discussed the use of hospice claims-reported principal hospice
diagnoses that fall under the ICD-9-CM classification, "Mental, Behavioral and
Neurodevelopmental Disorders." There are several codes that fall under this classification that
encompass multiple dementia diagnoses that are frequently reported principal hospice diagnoses

on hospice claims, but are not appropriate principal diagnoses per ICD-9-CM Coding Guidelines.

There are, however, other ICD-9-CM dementia codes, such as those for Alzheimer's disease and others, that fall under the ICD-9-CM classification, "Diseases of the Nervous System and Sense Organs" which are acceptable as principal diagnoses per ICD-9-CM coding guidelines.

Comment: One commenter expressed concern that "Lewy Body Dementia," "Fronto-temporal Dementia" and "Vascular Dementia" are no longer allowed as principal hospice diagnoses. Another commenter questioned what would be the recommendation if the hospice provider is unable to determine the cause of the dementia either from a lack of medical records or specific diagnostic work-up. One commenter asked if the LCD for "Alzheimer's Disease and Related Disorders" would be applicable to use for coding guidance.

Response: In the FY 2014 Hospice wage index and payment rate update proposed rule (78 FR 27823), we did not state the specific dementia conditions and their corresponding ICD-9-CM codes that fall under various coding and sequencing conventions in the ICD-9-CM Coding Guidelines. There are many codes for dementia conditions, including the neurological causes as well as the clinical mental and behavioral manifestations of the underlying condition. These dementia conditions and ICD-9-CM codes are too numerous to list within the context of the proposed and final rules but are found in the ICD-9-CM Official Guidelines for Coding and Reporting manual. However, we clarified that dementia codes can be found under two classifications in the ICD-9-CM Official Guidelines for Coding and Reporting, "Mental, Behavioral and Neurodevelopmental Disorders" and "Diseases of the Nervous System and Sense Organs." Per ICD-9-CM Coding Guidelines, several, but not all, of these ICD-9-CM dementia codes are considered manifestation codes, especially those dementia codes classified under "Mental, Behavioral and Neurodevelopmental Disorders". In accordance with the 2012 ICD-9-CM Coding Guidelines, "certain conditions have both an underlying etiology and multiple body

system manifestations due to the underlying etiology. For such conditions, the ICD-9-CM has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists, there is a "use additional code" note at the etiology code, and a "code first" note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes, etiology followed by manifestation." In most cases, these manifestation codes will have in the code title, "in diseases classified elsewhere" or "in conditions classified elsewhere." Codes with this in the title are a component of the etiology/manifestation convention. The codes with the phrase "in diseases classified elsewhere" or "in conditions classified elsewhere" in the title indicate that they are manifestation codes. "In diseases classified elsewhere" or "in conditions classified elsewhere" codes are never permitted to be used as first listed or principal diagnosis codes and they must be listed following the underlying condition. However, there are manifestation codes that do not have "in diseases classified elsewhere" or "in conditions classified elsewhere" in their title. For such codes a "use additional code" note would still be present, and the rules for coding sequencing still apply. We noted that several dementia codes which are not allowable as principal diagnoses per ICD-9-CM coding guidelines are under the classification of "Mental, Behavioral and Neurodevelopmental Disorders." According to the ICD-9-CM Coding Guidelines for "Mental, Behavioral and Neurodevelopmental Disorders", dementias that fall under this category are "most commonly a secondary manifestation of an underlying causal condition."

Two of the most frequently reported dementia codes on hospice claims fall under this manifestation/etiology convention: "dementia in conditions classified elsewhere with behavioral disturbance" and "dementia in conditions classified elsewhere without behavioral disturbance".

Per ICD-9-CM Coding Guidelines, these codes are not acceptable as a reported principal

diagnosis, and the underlying physical condition must be coded first. These codes can be used as additional or other diagnoses on the hospice claim. Additionally, two other frequently reported dementia codes on hospice claims have underlying disease-specific sequencing conventions: "senile dementia, uncomplicated" and "other persistent mental disorders due to conditions classified elsewhere". There are ICD-9-CM Coding Guidelines specific to each of these codes and these codes cannot be used as the principal diagnosis but can be reported as additional or other diagnoses on the hospice claim. Instructional notes regarding the sequencing convention for each of these codes can be found under each of these codes in the Tabular List within the ICD-9-CM Official Guidelines for Coding and Reporting. Therefore, it is imperative that hospice providers understand and follow ICD-9-CM Coding Guidelines and sequencing rules for all diagnoses and especially those noted above. We encourage hospice providers to pay particular attention to dementia coding as there are dementia codes found in more than one ICD-9-CM classification chapter, and there are multiple coding guidelines associated with these dementia conditions.

The clarification of these coding guidelines is not to determine eligibility for hospice services, but rather, these guidelines are to assist with the proper coding sequences for the hospice claims. Eligibility for Medicare hospice services continues to be based on the <u>prognosis</u> of the individual based on the clinical judgment of the certifying physician that the individual has a life expectancy of 6 months or less if the terminal condition runs its normal course. CMS does not make any recommendations as to what specific diagnoses to select from the ICD-9-CM Official Guidelines for Coding and Reporting for an individual beneficiary as these selections are to be determined by the certifying physician(s) based on the clinical record review and the comprehensive assessment. There are dementia diagnoses, including Alzheimer's Disease,

Lewy-Body Dementia, fronto-temporal dementia, and senile degeneration of the brain, to name a few, that are allowable as principal diagnoses per ICD-9-CM Coding Guidelines and are located under the classification of "Diseases of the Nervous System and Sense Organs" in the ICD-9-CM Official Guidelines for Coding and Reporting manual.

Some of the ICD-9-CM dementia diagnoses take into account that some dementia conditions may be unspecified in the event that a definitive diagnostic work-up was not or could not be performed. However, based on the present and historical clinical presentation of the individual, there are unspecified dementia diagnoses and corresponding ICD-9-CM codes that are acceptable as a principal diagnosis per ICD-9-CM Coding Guidelines. Most of these codes can be found under the classification, "Diseases of the Nervous System and Sense Organs." However, the expectation remains that the certifying physician will select the appropriate diagnoses and codes that determine the terminal prognosis of the individual and that are most contributory to the terminal decline.

4. Guidance on Coding of Principal and Other, Additional, and/or Co-existing Diagnoses

In the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule, we stated based on the ICD-9-CM Coding Guidelines, that the circumstances of an inpatient admission always govern the selection of principal diagnosis (78 FR 27833). The principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care." In analyzing frequently reported principal hospice diagnoses, data analysis revealed differences between reported principal hospice diagnoses and reported principal hospital diagnoses in patients who elected hospice within 3 days of discharge from the hospital. In addition, in the proposed rule we stated that our expectation is for hospice providers to report all

coexisting or additional diagnosis related to the terminal prognosis and related conditions.

<u>Comment</u>: Several commenters said that these statements could be interpreted to mean that the principal hospice diagnosis must always mirror the hospital diagnosis and while this is often the case, there are sometimes specific clinical scenarios in which this would not necessarily occur. The commenters requested further clarification so that hospice providers do not feel compelled to violate their own coding judgment just to replicate the inpatient hospital diagnoses based on "mandates" from CMS.

Response: In our statements regarding the guidelines governing the selection of the principal hospice diagnosis, they were made to provide additional guidance on the selection of the principal diagnosis for hospice providers based on the ICD-9-CM Coding Guidelines. We recognize that the principal hospice diagnosis may not mirror the inpatient hospital diagnosis in certain circumstances. The scenario below, provided by a commenter, is an example:

A patient was admitted to the hospital with a diagnosis of pneumonia. Upon diagnostic work-up, it was discovered that the patient had stage 4 lung cancer. The patient opted not to pursue curative treatment and was discharged to home with hospice services in place.

The principal hospice diagnosis selected for this patient was lung cancer.

This would be an appropriate principal hospice diagnosis, though it was not the same as the primary hospital diagnosis. However, in the FY 2014 hospice wage index and payment rate update proposed rule, we presented data analysis where the principal hospital diagnosis was a cancer diagnosis, but the hospice diagnosis was not. It would be expected that, in a cancer diagnosis, in which the individual received inpatient medical care for that diagnosis and was discharged home with hospice election within three days, that the principal hospice diagnosis would be the inpatient hospital diagnosis of cancer. However, to clarify, we are not requiring

that the principal hospice diagnosis always must be the exactly the same as the inpatient hospital diagnosis. We continue to reiterate that the certifying physician, using his or her expert clinical judgment and supporting documentation from the clinical records and the comprehensive assessment(s), will determine the most appropriate principal diagnosis, along with other, additional related diagnoses, that are contributing to the terminal prognosis of the individual. Our purpose in providing these statements in the proposed rule was to remind providers of the ICD-9-CM Coding Guidelines which state, to list first the diagnosis shown in the medical record to be chiefly responsible for the services provided and to list additional codes that describe any coexisting conditions.

Comment: One commenter questioned what the expectation is for the number of other, additional diagnoses that should be reported on the hospice claim. This commenter stated that it was not the hospice's standard to report diagnoses not related to the terminal prognosis on the hospice claim. Another commenter stated that hospice providers historically were "cautioned for potential enticement by covering too many diagnoses." A few commenters expressed concern about how CMS may use additional information of the secondary and tertiary diagnoses for complex patients.

Response: We do not require hospice's to report a specific number of diagnoses on the hospice claims. However, ICD-9-CM Coding Guidelines are specific in its instructions to providers to "code all documented conditions at the time of the encounter/visit, and require or affect patient care treatment or management." Therefore, we expect that hospice providers will adhere to these guidelines in reporting the appropriate diagnoses to more fully describe the Medicare hospice beneficiaries receiving care and services needed to palliate and manage their terminal conditions, based on the information from the comprehensive assessment and

individualized hospice plan of care. Our regulations at §418.200, hospices must provide all services reasonable and necessary for the palliation and management of the terminal illness and related conditions. As noted, we require hospices to provide virtually all the care that is needed by terminally ill patients. Therefore, unless there is clear evidence that a condition is unrelated to the terminal prognosis, all services would be considered related. It is also the responsibility of the hospice physician to document why a patient's medical need(s) would be unrelated to the terminal prognosis. We expect that hospice providers will use their best clinical judgment in determining which diagnoses and conditions are related to the terminal prognosis of the individual receiving hospice care and will report those diagnoses and conditions accordingly on the hospice claims.

In response to the comment regarding the diagnosis not being available at the time of referral, we understand that a diagnosis may not be provided at the time of hospice referral given the sometimes acute nature of a hospice referral. However, upon the hospice physician's review of the comprehensive assessment along with the other clinical records, the expectation is that a diagnosis for hospice claims coding should be determined based on this review along with the hospice physician's best clinical judgment as to the condition most contributory to the terminal prognosis.

Furthermore, the expectation is to provide the diagnostic codes on the claim to reflect the individual's clinical status regardless of the number of diagnoses to do so. There are an ample number of diagnosis fields on the hospice claims for reporting. Because the hospice reimbursement is a bundled per diem rate, there is no enticement for reporting too many.

The goal of requesting all of the related diagnoses on the hospice claim is to have a more accurate picture of the Medicare hospice beneficiary population. This accurate picture of the

Medicare hospice population will also help to ensure that any payment reform model that is considered is done so in a responsible and thoughtful manner to protect the viability, integrity, and intent of the Medicare Hospice Benefit and the care philosophy of the hospice industry.

5. Transition to ICD-10-CM

In the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule we reminded hospice providers of the upcoming transition from ICD-9-CM to ICD-10-CM on October 1, 2014. We provided additional information regarding the transition to ICD-10-CM that is available through the CMS website at:

http://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/icd10; and ICD-10-CM coding guidelines can be found on the CDC's website at www.cdc.gov/nchs/data/icd10/10cmguidelines2012.pdf.

<u>Comment</u>: We received multiple comments asking to suspend the enforcement of the clarifications of ICD-9-CM Coding Guidelines until the implementation of ICD-10-CM. It was stated that the preparation for the transition to ICD-10-CM was burdensome enough for hospice providers.

Response: The transition to ICD-10-CM has been discussed in previous hospice rules and notices, and the transition deadline for ICD-10-CM has already been pushed back until its current October 1, 2014 implementation date to allow for providers to have adequate time to prepare their administrative processes and systems. Additionally, in our regulations at 45 CFR 162.1002, the Secretary adopted the ICD-9-CM code set, including The Official ICD-9-CM Guidelines for Coding and Reporting. The CMS' Hospice Claims Processing manual (Pub 100-04, chapter 11) requires that hospice claims include other diagnoses "as required by ICD-9-CM Coding Guidelines". Furthermore, these ICD-9-CM Coding Guidelines have been existing and

longstanding policies that should be adhered to by all providers.

Other health care providers in both the inpatient and outpatient settings are required to follow these coding guidelines, and enforcement of these policies has been part of their payment systems for years. The expectation for hospice providers to follow those same guidelines is imperative to ensure continuity and quality of care throughout a Medicare beneficiary's health care continuum. Therefore, we stand by our clarifications regarding the ICD-9-CM Coding Guidelines and ICD-10-CM Coding Guidelines. However, in response to the comments received regarding the additional time needed to implement these coding clarification changes within their software systems, we will require these coding changes beginning on October 1, 2014, when all hospice claims submitted on or after October 1, 2014 will be subject to having claims returned if presented for payment with incorrect codes.

B. The Hospice Quality Reporting Program

1. Background and Statutory Authority

Section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program for hospices. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that FY. Depending on the amount of the annual update for a particular year, a reduction of 2 percentage points could result in the annual market basket update being less than 0.0 percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. Any reduction based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the Act, would apply only for the particular FY involved.

Any such reduction will not be cumulative and will not be taken into account in computing the payment amount for subsequent FYs.

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. The data must be submitted in a form, manner, and at a time specified by the Secretary. Any measures selected by the Secretary must have been endorsed by the consensus-based entity which holds a contract regarding performance measurement with the Secretary under section 1890(a) of the Act. This contract is currently held by the NQF. However, section 1814(i)(5)(D)(ii) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the consensus-based entity, the Secretary may specify measures that are not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary. Section 1814(i)(5)(D)(iii) of the Act requires that the Secretary publish selected measures applicable with respect to FY 2014 no later than October 1, 2012.

Quality Measures for Hospice Quality Reporting Program and Data Submission
 Requirements for Payment Year FY 2014

The successful development of a Hospice Quality Reporting Program (HQRP) that promotes the delivery of high quality healthcare services is our paramount concern. We seek to adopt measures for the HQRP that promote efficient and safer care. Our measure selection activities for the HQRP takes into consideration input we receive from the Measure Applications Partnership (MAP), convened by the National Quality Forum (NQF), as part of a pre-rulemaking process that we have established and are required to follow under section 1890A of the Act. The MAP is a public-private partnership comprised of multi-stakeholder groups convened by the

NQF for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890A(a)(3) of the Act. By February 1st of each year, the NQF must provide that input to CMS. Input from the MAP is located at: (http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx). For more details about the pre-rulemaking process, see the FY 2013 IPPS/LTCH PPS final rule (77 FR at 53376(August 31, 2012)).

We also take into account national priorities, such as those established by the National Priorities Partnership at (http://www.qualityforum.org/npp/), the HHS Strategic Plan http://www.hhs.gov/secretary/about/priorities/priorities.html), and the National Strategy for Quality Improvement in Healthcare located at (http://www.healthcare.gov/news/reports/nationalqualitystrategy032011.pdf).

To the extent practicable, we have sought to adopt measures that have been endorsed by the national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

As stated in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47302, 47320), to meet the quality reporting requirements for hospices for the FY 2014 payment determination as set forth in section 1814(i)(5) of the Act, we finalized the requirement that hospices report two measures:

• An NQF-endorsed measure that is related to pain management, NQF #0209. The data collection period for this measure was October 1, 2012 through December 31, 2012, and the data submission deadline was April 1, 2013. The data for this measure are collected at the patient level, but are reported to CMS in the aggregate for all patients cared for within the reporting period, regardless of payer.

• A structural measure that is not endorsed by NQF: Participation in a Quality

Assessment and Performance Improvement (QAPI) program that includes at least three quality
indicators related to patient care. The data collection period for this measure was October 1,
2012 through December 31, 2012, and the data submission deadline was January 31, 2013.

Hospices are not asked to report their level of performance on these patient care related
indicators, but simply to indicate that a QAPI program with patient care related indicators has
been implemented.

Hospices failing to report quality data before the specified deadline in 2013, will have their market basket update reduced by 2 percentage points in FY 2014. Hospice programs will be evaluated for purposes of the quality reporting program based on whether or not they submit data, and not based on their performance level on required measures.

For the FY 2014 payment determination, hospices were asked to provide identifying information, and then complete a web based data entry for the required measures. For hospices that could not complete the web based data entry, a downloadable data entry form was made available upon request. Electronic data submission will be required for the FY 2015 payment determination and beyond; there will be no other data submission method available.

Quality Measures for Hospice Quality Reporting Program and Data Submission
 Requirements for Payment Year FY 2015 and Beyond

In the November 8, 2012 CY 2013 Home Health Prospective Payment System Rate Update final rule (77 FR 67068, 67133), to meet the quality reporting requirements for hospices for the FY 2015 payment determination and each subsequent year, as set forth in section 1814(i)(5) of the Act, we finalized the requirement that hospices report two measures:

• The NOF-endorsed measure that is related to pain management, NOF #0209

• The structural measure: Participation in a Quality Assessment and Performance Improvement (QAPI) Program that includes at least three quality indicators related to patient care. We did not extend the requirement that hospices complete a check list of their patient care indicators and indicate the data sources they used for their quality indicators.

In the proposed rule for FY2014 (78 FR 27823), we proposed that the structural measure related to QAPI indicators and the NQF #0209 pain measure would not be required for the hospice quality reporting program beyond data submission for the FY 2015 payment determination. The original intent of the structural measure was for hospices to submit information about number, type, and data source of quality indicators used as a part of their QAPI Program. Data gathered as part of the structural measure were used to ascertain the breadth and context of existing hospice QAPI programs to inform future measure development activities including the data collection approach for the first year of required reporting (the reporting period which could result in payment reductions in FY 2014). To date, hospices have reported two cycles worth of structural measure data to CMS:

- Voluntary reporting period (submitted to CMS by January 31, 2012) For the voluntary reporting period hospices submitted free text data describing each quality indicator in their QAPI programs; data regarding number and data source of quality indicators were also submitted.
- FY 2014 (submitted to CMS by January 31, 2013) For the FY 2014 cycle, hospices submitted data about the topic areas of care addressed by quality indicators in their QAPI Programs, using a drop-down menu checklist rather than free text, in order to reduce burden. Data regarding number and data source of quality indicators were also submitted.

 CMS has analyzed data from both reporting periods. Findings from the voluntary reporting period showed that hospices use quality indicators that address a wide range of patient care

related topics and that there is great variation in how hospices collect and use "standardized" quality indicators. The majority of reported indicators addressed patient safety and physical symptom management. Likewise, findings from analysis of the FY 2014 structural measure data reiterated findings from the voluntary reporting period.

Other topics addressed included management of psychosocial aspects of care, bereavement and grief, communication, and care coordination. Overall, findings from both data collections of the structural measure have provided adequate information on hospice's patient care-related indicators making further reporting on the structural measure unnecessary.

Comment: We received several comments in favor of the proposal to remove the structural measure requirement beyond data submission for the FY 2015 payment determination. There were no comments in opposition to removing the structural measure requirement after FY 2015. One commenter indicated that CMS should make clear that it was only removing the structural measure requirement, not the QAPI program requirement from the Conditions of Participation.

Response: The results of the voluntary reporting period and the analysis of the FY 2014 structural measure data provided adequate information about hospices' patient care-related quality indicators. We are finalizing the proposal to remove the structural measure requirement beyond data submission for the FY 2015 payment determination. We are reiterating that the requirements regarding QAPI in the Conditions of Participation remain intact.

As stated above, in the proposed rule, we proposed that the NQF #0209 pain measure not be required for the hospice quality reporting program beyond data submission for the FY2015 payment determination. We determined that the NQF # 0209 measure as it is currently collected and reported by hospices is not suitable for long term use as part of the Hospice Quality

Reporting Program (HORP). In making this decision, we considered findings from the Voluntary Reporting Period and the Hospice Item Set pilot. Since the publication of the proposed rule, we examined data from the first year of reporting on the measure (impacting FY) 2014 APU determination). In addition, we considered stakeholder input including comments submitted during rulemaking, expert input from a Technical Expert Panel (TEP), and provider questions and comments submitted to the hospice quality help desk during the 2012/2013 data collection and reporting period. There are two central concerns with the NOF #0209 measure. First, the measure does not easily correspond with the clinical processes for pain management, resulting in variance in what hospices collect, aggregate, and report. This concern could potentially be addressed by extensive and ongoing provider training or standardizing data collection. However, even with extensive training and the use of a standardized item set during the pilot test, the data showed continued variance in implementation of the measure. Second, there is a high rate of patient exclusion due to patient ineligibility for the measure and patients' denying pain at the initial assessment. This high rate of patient exclusion from the measure results in a small denominator and creates validity concerns. These concerns cannot be addressed by training or standardizing data collection. We recognize the value of measuring hospices' ability to achieve patient comfort and the desire to include a patient outcome measure such as the NQF #0209 in the HQRP. By removing the requirement that hospices submit the NQF #0209 measure, pain comfort will not be measured as part of the HQRP. However, we plan to require that hospices collect data on two other measures that address care for pain. The standardized item set that CMS has developed contains data elements to collect 7 quality measures endorsed by NQF for hospice. Among these are two process measures related to pain: the NOF #1634, Pain Screening, and NOF #1637, Pain Assessment. However, while these

measures provide insight about screening and assessment of patients, they do not offer information about patient-reported comfort related to pain.

In the proposed rule, an alternative proposal was made to retain NQF #0209 until a more suitable outcome measure was available for use in the HQRP, to maintain a focus on achieving patient comfort. We also recognize the importance of adherence to standardized data collection specifications when producing measures for public reporting. We intend to work toward the HQRP's future inclusion of an improved pain outcome measure. We solicited comment on the removal of the checklist and data source questions from the structural measure, and the removal of the NQF #0209 measure. We also solicited comment on the alternative proposal of maintaining NQF #0209 until another pain outcome measure is available.

Comment: A large majority of comments received agreed with the proposal to remove the NQF #0209 pain measure from the HQRP because of the concerns with the measure as described above. Commenters stated that the measure is difficult to implement and does not correspond with clinical processes for pain management. One commenter suggested that there is not an issue with the data collection not corresponding to hospice clinical practice, but rather a learning curve phenomenon. Commenters also agreed that high rates of patient exclusion from the measure lead to validity issues. The majority of commenters were also against the alternate proposal to retain the NQF #0209 until an alternate pain outcome measure is developed, citing that continuing to collect it would be an unnecessary burden on providers. Some also commented that discontinuing data collection for the NQF #0209 pain measure after the CY 2013 data collection period would permit hospices more time to focus on preparing for the implementation of the Hospice Item Set (HIS) and other requirements. A few commenters indicated that the NQF #0209 should be retained. Commenters in favor of retaining the measure

stated that, though flawed, the measure has merit because it is an outcome measure. They also felt it has merit because it incorporates patient preferences for pain management and is meaningful to consumers. Commenters also stated that hospices invested a lot of time and energy to establish their data collection and submission processes for this measure. One commenter thought CMS should evaluate additional quarters of data submissions by hospices to fully evaluate the measure's validity before deciding whether to eliminate its use from the HQRP.

Response: Since the release of the proposed rule, we have analyzed the NQF #0209 pain measure data from the FY 2014 hospice reporting cycle. Results from the analysis support our central concerns with the NQF #0209 pain measure as stated above. Due to exclusions, a very small percentage of patients admitted to hospice would be represented by this quality measure, suggesting validity issues with the measure. FY 2014 data analysis shows that data errors affected approximately one-third of all hospices' data submissions despite the use of warning and error messages in the data submission system. In addition, the data showed that approximately 30 percent of the patients who were asked the initial comfort question ended up in the measure denominator (the denominator is set by patients who said "yes" to the initial comfort question). The data also showed that approximately 54 percent of hospices had 10 or fewer admissions during the data collection period (Q4 2012), indicating a denominator size problem that would affect the potential use of the measure for public reporting purposes in the future. We will post a document summarizing the findings related to the NQF #0209 measure on the cms.gov website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/index.html. The document includes findings from the Voluntary Reporting Period, the Hospice Item Set Pilot Test, and the FY 2014 national reporting

of the NQF #0209 data. These three sources of information along with stakeholder comments during the public comment period were considered in finalizing the proposal to discontinue the requirement that hospices report the NQF #0209 measure beyond FY 2015. We understand that hospices may choose to use the NQF #0209 as part of their ongoing quality improvement efforts. However, we believe that continuing to require hospices to report the NQF #0209 measure beyond FY 2015 is inappropriate and burdensome. We agree that outcome measures are essential to the HQRP. We are committed to developing an improved pain outcome measure and we will work toward the HQRP's future inclusion of an improved pain outcome measure. Although we appreciate the value of including an outcome measure as part of the HQRP, based on the majority of comments received and FY 2014 NQF #0209 data analysis findings, we are finalizing the proposal to discontinue use of the NQF #0209 pain measure after FY 2015 reporting. We will not finalize the alternate proposal to retain the NQF #0209 until another pain outcome measure is available.

4. Quality Measures for Hospice Quality Reporting Program for Payment Year FY 2016 and Beyond

As stated in the November 8, 2012 CY 2013 Home Health Prospective Payment System Rate Update final rule (77 FR 67068, 67133), we considered an expansion of the required measures to include additional measures endorsed by NQF. We also stated that to support the standardized collection and calculation of quality measures, collection of the needed data elements will require a standardized data collection instrument. We have developed and tested a hospice patient-level item set to be used by all hospices to collect and submit standardized data items about each patient admitted to hospice. We contracted with RTI International to support the development of the Hospice Item Set (HIS) for use as part of the HQRP. In developing the

HIS, RTI focused on the NQF endorsed measures that had evidence of use and/or testing with hospice providers. Most of these measures were initially developed during the PEACE (Prepare, Embrace, Attend, Communicate, and Empower) Project, which was funded by CMS to develop and test an initial set of quality measures for use in hospice and palliative care. The PEACE project, which ended in 2008, resulted in the identification of recommended quality measure and data collection tools that hospice providers could use in their Quality Assessment and Performance Improvement (QAPI) programs to assess quality of care and target areas for improvement. Additional information on the PEACE project can be found at http://www.thecarolinascenter.org/default.aspx?pageid=24.

Most of the measures endorsed by NQF are already widely in use by hospices nationwide as part of their internal Quality Reporting and Performance Improvement (QAPI) programs. Data we received from hospices during the Voluntary Reporting Period in 2011 showed that hospices had implemented and were using the PEACE measures. Some of the PEACE measures were endorsed by NQF in February, 2012, and are listed below with their NQF endorsement numbers. The HIS standardizes the collection of the data elements that are needed to calculate seven of the NQF endorsed measures. The HIS was pilot tested during the early summer of 2012. The primary objective of the pilot was to explore data collection methods and the feasibility of implementing a patient-level item set for possible future use as part of the HQRP.

In developing the standardized HIS, we considered comments offered in response to the July 13, 2012 CY 2013 Home Health Prospective Payment System Rate Update proposed rule (77 FR 41548, 41573). We have included data items that support the following NQF endorsed measures for hospice:

• NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen

- NQF #1634 Pain Screening
- NQF #1637 Pain Assessment
- NQF #1638 Dyspnea Treatment
- NQF #1639 Dyspnea Screening
- NOF #1641 Treatment Preferences
- NQF #1647 Beliefs/Values Addressed (if desired by the patient) (modified)

To achieve a comprehensive set of hospice quality measures available for widespread use for quality improvement and informed decision making, and to carry out our commitment to develop a quality reporting program for hospices that uses standardized methods to collect data needed to calculate quality measures, we proposed the implementation of the HIS in July 2014. We believe that to support the standardized collection and calculation of any or all of the hospice quality measures listed above, it is necessary to use a standardized data collection mechanism. The HIS was developed specifically for this data collection purpose. The HIS Paperwork Reduction Act (PRA) package is posted on the PRA area of the CMS.gov website at: https://www.cms.gov/Regulations-and-

Guidance/Legislation/PaperworkReductionActof1995/index.html.

We proposed that hospices begin the use and submission of the HIS in July 2014. To meet the quality reporting requirements for hospices for the FY 2016 payment determination and each subsequent year, we proposed regular and ongoing electronic submission of the HIS data for each patient admitted to hospice on or after July 1, 2014, regardless of payer. Hospices will be required to complete and submit an admission HIS and a discharge HIS for each patient. Hospices failing to report quality data via the HIS in 2014 will have their market basket update reduced by 2 percentage points in FY 2016. Hospice programs will be evaluated for purposes of

the quality reporting program based on whether or not they submit data, not on their performance level on required measures.

Comment: We received comments that were supportive of the implementation of the Hospice Item Set (HIS). Commenters agreed with the need for a standardized item set to collect patient level information that could be used to calculate the quality measures endorsed by the National Quality Forum (NQF) for hospice. However, commenters were concerned that the proposed July 1, 2014 date for starting submission of the HIS was too soon, and didn't allow for adequate time to prepare processes and systems for data collection, staff training, and other organizational preparations for implementation, particularly in the context of the other proposals in the rule such as the implementation of the hospice experience of care instrument.

Commenters noted that vendors would have less than 12 months to create software for providers to use to submit the HIS data. Commenters were concerned that there were too many changes coming in too short a time.

Response: We appreciate the general support of standardized data collection and the Hospice Item Set (HIS). We are aware of the effort hospices and vendors will have to make to prepare for implementation of the HIS. The HIS pilot showed that implementing the HIS is feasible, and that hospices are most likely already collecting the information needed to complete the HIS data items. A draft version of the HIS technical data specifications was posted on the CMS web site on May 24, 2013. Based on other provider settings (for example, Home Health Agencies and Nursing Homes), it is our experience that when there are changes to the draft version of data specification the changes are minor and few, if any, compared to the final version of the technical data specifications. Thus, vendors have been provided with more than adequate time (greater than 12 months) to develop products for their clients. We expect vendors to begin

reviewing the draft technical data specifications as soon as they are posted. We encourage vendors to submit questions and comments to the HIS technical email box:

HospiceTechnicalIssues@cms.hhs.gov. On July 16, 2013, CMS held a call specific for software developers and vendors regarding the HIS technical data specifications. We will hold additional vendor calls as needed to ensure that software vendors have the appropriate information to develop their own products for HIS. Software vendors should not be waiting for final technical data specifications to be posted to begin development of their own products. Therefore, we believe that vendors have been provided with adequate time and resources to meet the July 1, 2014 implementation date of the HIS.

CMS will provide free software for the HIS. We will make a beta version of the software available in May 2014 and the final version in June 2014. Providing a beta version for hospice agencies to download in May will allow their staff to become familiar with the functionality of the tool. We will provide training on the CMS HIS software and the submission process. We anticipate the training to occur in the spring of 2014. Furthermore, in cases where a hospice has purchased vendor software and the product is not available by July 1, 2014, the hospice may download the CMS software and submit records to the Quality Improvement and Evaluation System (QIES) Assessment and Submission Processing (ASAP) system as required. Thus, hospices will be able to comply with the July 1, 2014 implementation date of the HIS. We are finalizing implementation of the HIS on July 1, 2014.

<u>Comment</u>: Several commenters expressed concern over the "100 percent submission requirement" of the HIS and stated that exceptions for natural disasters and other extenuating circumstances should be allowed. In addition, a few commenters expressed concern that a

hospice would be penalized if even one submission was missed, and that there needs to be a receipt process that would provide proof of data submission.

Response: Submission of the HIS on all patients admitted to hospice, regardless of payer, is expected. As is common in other quality reporting programs, we will propose to make accommodations in the case of natural disaster or other extenuating circumstances in next year's rulemaking. In addition, the data submission system will include validation and receipt processes that will serve as evidence of submission.

Comment: Some commenters indicated that they support the implementation of the HIS and the endorsed measures that can be calculated from the items on the HIS. However, while overall supportive of the measures and the HIS, they also indicated concern about the length of stay exclusion in the endorsed measures that will be calculated from the HIS. Commenters were also concerned that there were no outcome measures that will be calculated from the HIS. We also received a few comments indicating concern over other measure specifications (for example, additional exclusions for measures).

Response: To comply with the requirements of the Affordable Care Act, CMS seeks to implement meaningful quality measures with demonstrated scientific acceptability that have been endorsed by an endorsing body, currently the NQF. Thus, we are somewhat, but not completely constrained by the availability of endorsed hospice quality measures. In addition, in selecting and implementing measures, we are constrained by the measures specifications of the endorsed measures. All of the measures that will be implemented are endorsed with a 7-day length of stay exclusion as part of the measure specifications. Section 1841(i)(5)(D) of the Act requires us to be deferential to measures approved by an endorsing body such as the NQF. However, we agree that the length of stay exclusion in particular is of concern because it

effectively excludes an important segment of hospice patients from the measures. We plan to analyze HIS data to continue to assess the scientific acceptability of the measures and are willing to work with measure developers and stewards to make modifications to measures where needed. In addition, we support the development of additional hospice quality measures, particularly outcome measures, and will seek opportunities to use outcome measures as they are developed and validated.

<u>Comment:</u> We received a few comments indicating concern over the potential burden of the HIS on patients and families.

Response: The HIS is a set of data elements that can be used to calculate 7 NQF endorsed quality measures. The HIS is <u>not</u> a patient assessment and it will not be administered to the patient and/or family or caregivers during the initial assessment visit. The HIS is not intended to replace a hospice's current initial patient assessment. The HIS pilot demonstrated that hospices use a variety of patient assessment forms during the initial patient assessment; all hospices were able to crosswalk items from their patient assessment forms to the HIS data elements, and complete the HIS items. Therefore, the HIS did not add items to the hospice's customary patient initial assessment, and did not present an additional burden to the patient and/or family or caregivers.

<u>Comment</u>: A few commenters suggested removing the discharge HIS, indicating that the items on the discharge HIS are only administrative, and provide no additional value in terms of the quality measures while adding burden of completion to the hospice. Other commenters indicated that they were pleased to see the proposal of an admission and discharge HIS.

Response: The discharge HIS is needed to provide an end date for the episode of care, and to establish the length of stay exclusion for patients whose hospice stay was less than 7 days.

The discharge HIS items are minimal, but necessary for accurate records in the CMS data system and potentially for the providers' use with their own QAPI activities. Vendor software would pre-populate the majority of these items and the hospice would only code a few of the items on the discharge HIS; burden on hospices would be reduced as a result.

<u>Comment:</u> A few commenters voiced concerns about potential ceiling effects with the NQF quality measures stating that measures may "top out." Two commenters stated that NQF #1634 Pain Screening should not be considered for use in the quality reporting program, citing concerns about ceiling effects with the measure.

Response: We recognize the commenters' concerns about the appropriateness of use of quality measures that have "topped out," demonstrating ceiling effects. Ceiling effects on quality measures would indicate that there is little room for improvement on the particular quality measures across providers, rendering the measures of little use in measuring quality. There is currently no national data available to determine whether any of the proposed measures demonstrate ceiling effects. We will analyze data submitted to determine validity and reliability of measures, and part of this analysis will include analyzing for ceiling effects. We will determine appropriateness of measures for retention in the quality reporting program based on these analyses. We appreciate commenters' concerns about NQF #1634 Pain Screening. However, NQF #1634 Pain Screening and NQF #1637 Pain Assessment are paired measures meaning NQF #1634 is necessary to generate the denominator for NQF #1637.

<u>Comment</u>: Two comments stated that items for the NQF #1641 and #1647 should appear on the discharge HIS to meet measure specifications.

Response: The NQF #1641 measure endorsement form does not specify a time window for the measure numerator. The commenters are correct that the NQF #1647 measure

endorsement form does specify that the numerator criteria can be met any time during the period the patient is enrolled in the hospice program. We have consulted NQF about our proposal to capture the data on the admission HIS, and have received guidance that by limiting the time window in this way, we are proposing to use a "modification of the NQF #1647" measure. We have opted to include the relevant items for both the NQF #1641 and the NQF #1647 on the Admission HIS, even though the measure specifications for the NQF #1647 permit the numerator condition to be met at any time during the hospice episode of care. For multiple reasons, CMS has opted to include the NOF #1647 measure items as part of the Admission HIS, reflecting the initial period of time the patient is in hospice care. Addressing patients' values/beliefs and preferences for treatment by providing an opportunity for patients and families to discuss their preferences during the comprehensive assessment period is an important step in ensuring the delivery of hospice care that is patient and family-centered. Including the NQF #1647 measure items as part of the Admission HIS also aligns with the Conditions of Participation for hospices at §418.54(c), which state that the comprehensive assessment "must identify the physical, psychosocial, emotional and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process...." We recognize that the discussion can take place at any time in the course of a patient's hospice care but believe the patient should be offered the opportunity to address these concerns in the early days of care when they are more likely to be able to do so. We consider it best practice. We have chosen this approach also because it allows the gathering of the data for the measure closer to "real time" in terms of usual hospice assessment and workflow and because this approach will likely improve accuracy and reduce burden to the provider. If these items were on the discharge HIS, hospices would have to review the entire episode of care

documentation to find the information needed to complete the relevant items on the HIS. We worked with the measure developer to ensure that the intent of the measure is still met with the HIS admission data collection. We will monitor the performance over time to inform future evaluation for maintenance of the measure's endorsement. We will proceed with the collection of the NQF #1641 measure and the modified NQF #1647 measure as part of the Admission HIS.

<u>Comment</u>: We received a few comments regarding what should count towards the numerator for NQF #1641 (Treatment Preferences). Commenters suggested that review of advance directives count in the numerator for these items.

Response: Discussion of patient preferences is important to ensure that care is individualized, patient and family centered, and consistent with patient and/or family preferences. The intent of the NQF #1641 measure is to ensure that hospices engage patients and families in opportunities to discuss their treatment preferences. Hospices meet the #1641 numerator requirements by asking the patient and/or family about their preferences and documenting that a discussion of preferences occurred, or by documenting that the patient and/or family did not wish to discuss their preferences. The measure endorsement forms clearly state that the measure is meant to capture evidence of communication and discussion. Prior to implementation of the HIS, we will provide hospices with guidance and training materials, including a detailed user guide.

<u>Comment</u>: We received a comment that NQF #1641 (Treatment Preferences) does not mention cardiopulmonary resuscitation (CPR) or hospitalization.

Response: The measure specifications as endorsed by NQF do not clearly define what constitutes preferences for life-sustaining treatment. As such, we included data items F2000 (CPR Preference) and F2200 (Hospitalization Preference) in the HIS to provide clarification and

improve usability. These specifics are important to measure maintenance and development and does not stray from the measure specifications. We will provide guidance and training materials, including a detailed user guide for hospices prior to implementation of the HIS.

<u>Comment</u>: For NQF #1647, one commenter questioned which hospice staff would be eligible to ask the patient about concerns related to beliefs and values to satisfy the numerator for the measure. This commenter questions if a social worker or bereavement staff member could collect the data or if it had to be a chaplain.

Response: The measure specifications for NQF #1647 require documentation of a discussion between the patient and/or family and a member of the interdisciplinary team or clergy or pastoral worker, or documentation that the patient/family declined to discuss. We will provide guidance and training materials, including a detailed user guide, to hospices prior to implementation of the HIS.

<u>Comment</u>: We received comments providing input about specific items on the HIS.

Commenters offered suggestions on items in Sections A, F, I, J, N, and Z of the HIS.

Response: We appreciate the comments received about specific items in the HIS. The items in Section A are a subset of those that appear and are standardized across data submission vehicles in multiple CMS quality reporting programs; they are needed for adequate record identification in CMS systems. Items in Sections F, I, J, and N are all necessary to establish the numerator and/or denominator; meet other measure specifications for the 7 NQF endorsed measures that can be calculated from the HIS; or for purposes of future potential risk adjustment to the measures.

<u>Comment</u>: We received several comments regarding who the hospice must speak with about items in Section F (Preferences) to meet the numerator condition for the corresponding

measures. A few commenters noted that not all patients have caregivers.

Response: For items F2000, F2100, and F2200, the hospice must ask the patient or the patient's representative if the patient is unable to self-report. The responsible party may or may not be a family member or caregiver. We will provide guidance and training materials, including a detailed user guide to hospices prior to implementation of the HIS.

<u>Comment</u>: We received several comments regarding Section I (Active Diagnoses) and item I0010 (Principal Diagnosis) that appears in this section. Some commenters felt the item did not include enough diagnoses to be useful and that principal diagnoses was not relevant to the measures. One commenter suggested that we obtain this data from claims or Program for Evaluating Payment Patterns Electronic Report (PEPPER) reports.

Response: Disease processes and conditions impact service delivery. Cancer and dementia/Alzheimer's Disease are two of the most common principal diagnoses among hospice patients. We believe that this item is important for measure maintenance and development. The HIS applies to all payers, which is why CMS is not relying on claims or other available data sources. To limit the burden on hospice providers we chose to limit the diagnostic categories.

Comment: We received comments that J0900 (Pain Screening) and J0910 (Comprehensive Pain Assessment) went beyond the measures specifications for NQF #1634 and NQF #1637. Some commenters did not understand the purpose of J0900D (the patient's pain severity rating); others argued that J0900D should be removed from the item set because it incorrectly implies that a clinician's opinion of pain severity is an acceptable datum. Others questioned the inclusion of J0910C (Comprehensive Pain Assessment included).

Response: The NQF # 1634 and 1637 are "paired measures". The NQF #1634 forms the denominator for the NQF #1637 measure. The measure specifications for NQF #1634 require

that patients must be screened for the presence or absence of pain (and if present, a rating of its severity) using a standardized tool. The measure specifications do not require hospices to use one particular tool or clinical approach, in recognition of prior stakeholder input that indicated it is important to allow clinicians to select and use the appropriate screening tool on a case-by-case basis. The HIS is not a patient assessment; it is an item set designed to collect data elements that can be used to calculate NQF endorsed measures, including NQF #1634 and #1637. As a result, item J0900D is needed to establish whether or not the standardized screening tool selected and used by the clinician indicated that the patient had pain. Details of how to code item J0900D will be provided in the User Guide. CMS has involved the measure steward in developing that User Guide. J0900 D is also needed because it forms the denominator for NQF #1637, pain comprehensive assessment. The measure specifications for NQF #1637 indicate that a comprehensive clinical assessment should include 5 of the following 7 characteristics of pain: location, severity, character, duration, frequency, what relieves or worsens the pain, and the effect on function or quality of life. J0910C provides a checklist of these 7 items and forms the numerator for NQF #1637.

Comment: We received several comments regarding J0900 (Pain Screening) and J0910 (Pain Assessment). Some commenters expressed that we should provide more clarity on acceptable pain screening tools and determining patient pain severity. Regarding J0910C (Comprehensive Pain Assessment included), one commenter indicated that finding the elements of the comprehensive pain assessment in the medical record would be tedious.

Response: The measure specifications for NQF #1634 (Pain Screening) require that patients must be screened for the presence or absence of pain (and if present, a rating of its severity) using a standardized tool. The HIS is not a patient assessment, and we do not want to

be overly prescriptive in which standardized pain screening tools hospices use or how patient pain is rated. Thus, the items listed in J0900C (Type of standardized pain screening tool used) are not specific screening tools in and of themselves. Instead they are tools that may be utilized for the assessment of pain severity. Item J0910C (Comprehensive pain assessment included) helps form the numerator for NQF #1637 (Pain Assessment) and must be retained. We will provide guidance and training materials, including a detailed user guide to hospices prior to implementation of the HIS.

<u>Comment</u>: We received comments on J2030 (Screening for Shortness of Breath) and J2040 (Treatment for Shortness of Breath). One commenter suggested that the respiratory screening should require evaluation of shortness of breath upon exertion. Another commenter questioned the purpose of J2040C (Type(s) of treatment for shortness of breath initiated).

Response: The measure specifications for NQF #1639 (Dyspnea Screening) do not require that the respiratory screening include evaluation upon exertion. J2040C helps form the numerator for NQF #1639. We believe that this item will improve usability by indicating the treatments/types of treatment that may be considered treatment for shortness of breath for purposes of the measure numerator condition. The HIS is not a patient assessment, and we do not want to be overly prescriptive in which screening tools hospices use, particularly for shortness of breath where there is no accepted standardized screening or assessment tool. We will provide guidance and training materials, including a detailed user guide to hospices prior to implementation of the HIS.

<u>Comment</u>: One commenter wanted to know when N0520 (Bowel Regimen) required a response.

Response: As noted on the draft HIS, providers will respond to the bowel items if a

scheduled opioid and/or a PRN opioid is initiated or continued.

<u>Comment</u>: We received several comments related to Section Z (Record Administration), particularly item Z0400 (Signature(s) of Person(s) Completing the Record). Commenters were unclear on the purpose of this section and how Z0400 should be completed.

Response: The items in Section Z appear in and are standardized across data submission vehicles in multiple CMS quality reporting programs. This section allows providers to verify, internally, the individuals responsible for completing the HIS (that is the abstracters, not those completing the patient assessment). In accordance with processes used in other care settings, it is suggested that the signature page of Section Z be retained by the hospice in accordance with the hospice's policies and procedures related to patient information and clinical records.

Comment: Several commenters inquired about future guidance and training on the HIS.

Response: We will provide guidance and training materials, including a detailed user guide, to hospices prior to implementation of the HIS. We plan to provide Hospices with further information and details about use of the HIS. We will provide this information through venues such as postings on the Hospice Quality Reporting Program webpage, Open Door Forums, announcements in the CMS E-News, provider training, and National Provider calls. Electronic data submission will be required for HIS submission in CY 2014 and beyond; there will be no other data submission method available. We will make available submission software for the HIS to hospices at no cost. We will also provide reports to individual hospices on their performance on the measures calculated from data submitted via the HIS. The specifics of the reporting system and precisely when specific measures will be made available have not yet been determined. We will report to providers on the following measures on a schedule to be determined:

• NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen

• NQF #1634 Pain Screening

• NQF #1637 Pain Assessment

• NQF #1638 Dyspnea Treatment

• NQF #1639 Dyspnea Screening

• NQF #1641 Treatment Preferences

• NQF #1647 Beliefs/Values Addressed (if desired by the patient)

Table 6. Summary Tables:

Finalized in the CY 2013 HH PPS Final Rule				
Data Collection	Data Submission	APU Impact	Measure Name	
1/1/2013 -	4/1/2014	FY 2015	Structural /QAPI measure	
12/31/2013		(10/1/2014)	NQF #0209	

Finalized in this Final Rule				
Data Collection	Data Submission	APU Impact	Measure Name	
7/1/2014 —	Rolling	FY 2016	Hospice and Palliative Care – Pain Screening, NQF	
12/31/2014		(10/1/2015)	#1634	
7/1/2014 —	Rolling	FY 2016	Hospice and Palliative Care – Pain Assessment, NQF	
12/31/2014		(10/1/2015)	#1637	
7/1/2014 —	Rolling	FY 2016	Hospice and Palliative Care – Dyspnea Screening,	
12/31/2014		(10/1/2015)	NQF #1639	
7/1/2014 —	Rolling	FY 2016	Hospice and Palliative Care – Dyspnea Treatment,	
12/31/2014		(10/1/2015)	NQF #1638	
7/1/2014 —	Rolling	FY 2016	Patients Treated with an Opioid who are Given a Bowel	
12/31/2014		(10/1/2015)	Regimen, NQF #1617	
7/1/2014 -	Rolling	FY 2016	Hospice and Palliative Care – Treatment Preferences,	
12/31/2014		(10/1/2015)	NQF #1641	
7/1/2014 —	Rolling	FY 2016	Beliefs/Values Addressed (if desired by patient),	
12/31/2014		(10/1/2015)	modified NQF #1647	

As stated in the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47302, 47320), we finalized that all hospice quality reporting periods subsequent to that for Payment

Year FY 2014 will be based on a CY instead of a calendar quarter and for FY 2015 and beyond, the data submission deadline will be April 1st of each year. The implementation of the HIS in July 2014 will negate the CY data collection requirement and the April 1st data submission deadline. We will provide details on data collection and submission timing prior to implementation of the HIS.

5. Public Availability of Data Submitted

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by hospices available to the public. The procedures ensure that a hospice will have the opportunity to review the data regarding the hospice's respective program before it is made public. In addition, under section 1814(i)(5)(E) of the Act, the Secretary is authorized to report quality measures that relate to services furnished by a hospice on the CMS website. We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to developing the necessary systems for public reporting of hospice quality data. We also recognize it is essential that the data made available to the public be meaningful and that comparing performance between hospices requires that measures be constructed from data collected in a standardized and uniform manner. The development and implementation of a standardized data set for hospices must precede public reporting of hospice quality measures. Once hospices have implemented the standardized data collection approach, we will have the data needed to establish the scientific soundness of the quality measures that can be calculated using the standardized data collection. It is critical to establish the reliability and validity of the measures prior to public reporting in order to demonstrate the ability of the measures to distinguish the quality of services provided. To establish reliability and validity of the quality measures, at least four quarters of data will

need to be analyzed. Typically the first two quarters of data reflect the learning curve of the providers as they adopt a standardized data collection; these data are not used to establish reliability and validity. This means that the data from O3 and O4 CY 2014 will not be used for assessing validity and reliability of the quality measures. Data collected by hospices during Q 1, 2 and 3 CY 2015 will be analyzed starting in CY 2015. Decisions about whether to report some or all of the quality measures publicly will be based on the findings of analysis of the CY 2015 data. In addition, as noted, the Affordable Care Act requires that reporting be made public on a CMS website and that providers have an opportunity to review their data prior to public reporting. We will develop the infrastructure for public reporting, and provide hospices an opportunity to review their data. In light of all the steps required prior to data being publicly reported, we anticipate that public reporting will not be implemented in FY 2016. Public reporting may occur during the FY 2018 APU year, allowing ample time for data analysis, review of measures' appropriateness for use for public reporting, and allowing hospices the required time to review their own data prior to public reporting. We will announce the timeline for public reporting of data in future rulemaking. We welcome public comment on what we should consider when developing future proposals related to public reporting.

Comment: We received a few comments regarding what should be considered in developing future proposals related to public reporting of hospice quality data. Commenters were in favor of public reporting, and indicated that they felt it was time to make this information available to consumers. Commenters also indicated that they appreciate the opportunity to review their data prior to the initiation of public reporting, and CMS's efforts to ensure that public reporting would not occur before adequate data analysis had taken place to establish the suitability of the measures for public reporting purposes. A few commenters suggested that

outcome measures and measures from the family experiences of hospice care survey would be more meaningful for public reporting than the measures from the HIS. Several commenters had concerns about which of the NQF measures proposed would be appropriate for public reporting. Commenters noted that all of the NQF measures proposed were process measures and it may "take effort" for the public to understand the relationship of process measures to quality of care. One commenter stated that a comprehensive explanation of this relationship should be provided to the public.

Response: We appreciate and recognize commenters' concerns about appropriateness of quality measures for public reporting. As stated in the proposed rule, we will analyze data for validity and reliability of quality measures and review measures' appropriateness for public reporting prior to determining which measures will be publicly reported. Moreover, we appreciate the suggestion to provide a comprehensive explanation of relationships between quality measures selected for public reporting and quality of care. We will consider this suggestion when developing processes, procedures and future proposals for public reporting. We also recognize the importance of outcome data, both for quality measurement and for public reporting. We also reiterate that we are committed to seeking opportunities to use outcome measures – both as part of the quality reporting program and for public report --- as they are developed and become endorsed by NQF.

6. The CMS Hospice Experience of Care Survey for the FY 2017 Payment Determination and that of Subsequent Fiscal Years

Background

In the CY 2013 Home Health Prospective Payment System Rate Update final rule (77 FR 67135), we stated that were considering the use of a patient/family experience of care survey in

addition to other hospice quality of care (clinical) measures. We have developed a draft Hospice Experience of Care Survey questionnaire drawing heavily on questionnaires in the public domain such as the Family Evaluation of Hospice Care (FEHC). We are testing the draft survey in a national field test in fall 2013. The Hospice Experience of Care Survey will treat the dying patient and his or her informal caregivers (family members or friends) as the unit of care.

Before the development of this survey, there was no official national standard experience of care survey that included standard survey administration protocols. The Hospice Experience of Care Survey will include detailed survey administration protocols which will allow for comparisons across hospices. The survey will focus on topics that are important to hospice users and for which informal caregivers are the best source for gathering this information. In addition, the "About You" section of the instrument includes demographic characteristics of the patients and their caregivers which can be used to feed into case mix adjustments of the publicly reported data.

Description of the Survey

The Hospice Experience of Care Survey will seek information from informal caregivers of patients who died while enrolled in hospices. We plan to field the questionnaires after the patient's death. Fielding timelines will be established to give the respondent some recovery time (two to three months), while simultaneously not delaying so long that the respondent is likely to forget details of the hospice experience. Caregivers will be presented with a set of standardized questions about their own experiences and the experiences of the patient in hospice care. During national implementation of this survey, hospices will be required to offer the survey, but individual caregivers will respond only if they voluntarily chose to do so.

The Hospice Experience of Care Survey captures such topics as hospice provider communications with patients and family members, hospice provider care, and patient and family member characteristics. The survey will allow the informal caregiver (family member or friend) to provide an overall rating of the hospice care their patient received, and will ask if they will recommend "this hospice" to others.

The Hospice Experience of Care Survey is following the principles used in the development of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) surveys. Therefore, we are--

- Obtaining input from consumers and stakeholders regarding how hospice patients perceive hospice care and what elements in hospice programs are of greatest importance to patients and informal caregivers.
- Drafting a version of the hospice questionnaire that will be cognitively tested with a small number of respondents in both English and Spanish. This type of testing will allow us to assess how respondents interpret and respond to individual questionnaire items.
- Providing a field test of the Hospice Experience of Care Survey instrument after the development of an initial questionnaire is completed. This field test will allow us to review survey implementation procedures and use statistical analysis of the survey results to select the final set of questions. In addition, it will allow us to select variables which may be used in the case mix adjustment of survey results for public reporting.

The Hospice Experience of Care Survey, as well as the CAHPS® family of surveys, focuses on patient perspectives on the experience of care, rather than on patient satisfaction.

CAHPS® data complements other data, including clinical measures. CAHPS® surveys are specifically intended to focus on issues where the patient (or in this case the caregiver) is the best

source of information. We intend the Hospice Experience of Care Survey to have a similar focus. Once the survey is final, we will submit it for CAHPS® endorsement and National Quality Forum endorsement.

We plan to move forward with a model of survey administration in which we will approve and train survey vendors to administer the survey on behalf of hospices. This will be very similar to the models that we use for Hospital CAHPS® (HCAHPS) and Home Health CAHPS® (HHCAHPS). Hospices will be required to contract with an approved survey vendor and to provide the sampling frame to the approved vendor on a monthly basis.

Participation Requirements for the Survey begin in CY 2015 for the FY 2017 Payment

We proposed that we would begin required implementation of the survey in January 2015 in the FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform proposed rule (78 FR 27823, published May 10, 2013). We are finalizing the proposed timeline due to the importance of the caregiver's voice. Beginning in first quarter of CY 2015, hospices will be required to conduct a dry run of the survey for at least one month in January 2015, February 2015, or March 2015. Beginning in April 2015, all hospices will be required to participate in the survey on an ongoing basis. The one "dry run month," plus the nine months of April 2015 to December 2015 participation, will be required to meet the pay for reporting requirement of the Hospice Quality Reporting Program for the FY 2017 annual payment update.

Approved Hospice Experience of Care Survey vendors will submit data on the hospice's behalf to the CMS hospice patient experience of care survey data center. The deadlines for data submission have not yet been finalized. For the "dry run" the survey vendor would follow all the national implementation procedures, but the data would not be publicly reported. The dry run

would provide hospices and their vendors with the opportunity to work together under "test" circumstances. We will allow exemptions for very small hospices. Hospices that have fewer than 50 unduplicated or unique deceased patients in the period from January 1, 2014 through December 31, 2014 will be exempt from the Hospice Experience of Care Survey data collection and reporting requirements for the FY 2017 payment determination. The hospices would be required to submit their patient counts for the period of January 1, 2014 through December 31, 2014 to CMS. The due date for the participation exemption form will be stated in next year's rule. To qualify for the small size exemption, hospices will need to submit to CMS their patient counts annually for each future APU period.

As part of the national implementation, we will develop technical specifications for vendors to follow and will issue a detailed survey guidelines manual prior to the dry run months.

In addition, there will be a website devoted specifically to the Hospice Experience of Care Survey. It will include information and updates regarding survey implementation and technical assistance. Hospices interested in viewing similar model websites are encouraged to visit the HCAHPS website at www.hcahpsonline.org or the HHCAHPS website at https://homehealthcahps.org. On these websites, viewers can see and download the detailed manuals about the surveys (the Quality Assurance Guidelines for Hospital CAHPS® and the Protocols and Guidelines Manual for Home Health Care CAHPS®), as well as obtain information about the surveys' histories, data submission information, and survey updates.

Consistent with our other implemented surveys, we will provide an email address and toll-free telephone number for technical assistance.

The Affordable Care Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that

does not comply with the quality data submission requirements with respect to the FY. Any such reduction would not be cumulative and would not be taken into account in computing the payment amount for subsequent FYs. In the November 8, 2012 CY 2013 Home Health Prospective Payment System final rule (77 FR 67068), it was stated that all hospice quality reporting periods subsequent to that for Payment Year 2014 would be based on a CY rather than on a FY. We are finalizing adding the Hospice Experience of Care Survey to the Hospice Quality Reporting Program requirements for the FY 2017 payment determination. To meet the FY 2017 requirements, hospices would participate in a dry run for at least 1 month of the first quarter of CY 2015 (January 2015, February 2015, March 2015) and hospices must collect the survey data on a monthly basis for the months of April 1, 2015 through December 31, 2015 in order to qualify for the full APU.

The following is a summary of the comments we received regarding the Hospice Experience of Care Survey proposal.

<u>Comment</u>: We received a number of comments that the timeline for implementation of the Hospice Experience of Care Survey placed it too close in proximity to the implementation of the HIS items and that there should be a gap of at least 12 months between the HIS implementation and the survey implementation dates.

Response: We carefully reviewed the comments asking for a delay in the timing of the national implementation of the Hospice Experience of Care Survey. However, we concluded that obtaining data from caregivers is so important that we cannot delay. As proposed we will begin with a dry run in the first quarter of 2015. Continuous data collection will begin April, 1, 2015 for the 2017 APU.

Comment: We received comments that there are financial and administrative burdens on hospices participation in the Hospice Experience of Care Survey. Commenters also stated that the financial burden of participation would outweigh the 2 percent reduction in the annual payment update that would be given to non-participating hospices. We also received comments stating that this would require more staffing and the development of a process to handle the implementation of the survey and comments that this is a burden to small hospices. We received a comment asking if hospices can self-administer the survey to save costs in implementing the hospice survey. In addition, we received a comment that the Family Evaluation of Hospice Care (FEHC) survey does not pose a financial burden to hospices because the FEHC survey is a benefit of National Hospice and Palliative Care Organization (NHPCO) membership.

Response: We appreciate the comments concerning that the proposed survey is a financial burden to participating hospices. We are using the same survey implementation model that we use for other CAHPS® surveys where providers pay approved survey vendors to conduct the data collection on their behalf and CMS pays for the survey vendor training, technical support and assistance for hospices and their approved survey vendors, oversight of the approved survey vendors, the public reporting of the data, and the data analysis of the hospice survey data. Before national implementation begins in 2015, hospices are strongly encouraged to shop around for the best cost value for them before contracting with an approved survey vendor to conduct the Hospice Experience of Care Survey on their behalf. Hospices cannot self-administer the survey because we need to eliminate any potential bias in the administration of the survey. We do not believe that the annual burden to hospices will exceed the annual burden and costs that we see in the implementation of HHCAHPS. Basically, once national implementation starts, hospices will need to choose a vendor and contract with them, and then they will be responsible

on a monthly basis to produce a file of all the caregivers (the persons on the records for the hospice patients) for hospice patients who died in the past month. We are not surveying people who have living hospice patients. We cannot fully comment on whether the survey costs to the individual hospice providers will outweigh the costs of the loss of 2 percent of the APU. However, most survey costs will be much less than the loss of the 2 percent reduction in the APU. Small hospices serving 50 or fewer patients in an annual period will complete (annually) a Participation Exemption Request Form so that they will not incur survey costs. The CMS hospice survey will require the approved survey vendors to implement the survey in accordance to a uniform set of protocols and guidelines to assure consistency in the survey administration, in the implementation of other CMS CAHPS® surveys, such as HCAHPS, and HHCAHPS.

<u>Comment</u>: We received comments that the draft hospice experience of care survey instrument is too long and "daunting" to read and respond to.

Response: This is a survey that is going to be used in a national field test in fall 2013. There are more questions in this test survey than we intend to keep in the final survey. We anticipate that we will eliminate questions that do not contribute to the composites measuring key areas of the hospice care experience. We do anticipate keeping all of the demographic questions, because they will be used to adjust the results for differences in the mix of patients across hospices and for analysis of disparities of care. It is important that the data are adjusted to ensure accurate comparisons across hospices. We actually anticipate that the final survey instrument will be significantly shorter than the FEHC, which has 54 items, and a shorter instrument will translate into lower vendor costs for the participating hospices. To give an example of this, the field test version of the HHCAHPS survey had 54 items and the final approved version of the survey that we use today, has 34 items.

<u>Comment</u>: We received a comment expressing the preference that NHPCO be allowed to be a survey vendor for the Hospice Experience of Care Survey.

Response: We will be using survey vendor eligibility criteria that are very similar or identical to our other CAHPS® surveys, and if NHPCO meets the stated survey vendor eligibility criteria then we welcome NHPCO to complete the survey vendor application for the hospice experience of care survey.

<u>Comment</u>: We received comments that we are administering the survey too close to the death of the patient.

Response: We thank you for this comment. We are sensitive that a survey about this issue will be difficult for the families and friends of their loved ones who have passed, especially in the first year following the deaths. We anticipate administering the survey about two or three months following the deaths of the hospice patients. We are hesitant about waiting too long following the deaths because the survey respondents may forget the details of the hospice experiences if the survey is administered too long following the deaths.

<u>Comment</u>: We received several comments supporting CMS for developing a new survey instrument that is independent of existing hospice survey instruments, and that has the uniform survey implementation guidelines of the CAHPS[®] surveys.

Response: We appreciate this support of the CMS survey instrument. We are following the CAHPS® guidelines and we will apply for CAHPS® endorsement as well as the endorsement of the National Quality Forum. Commenters supporting us noted that the final survey instrument will be shorter and that we will allow flexibilities in the implementation of the survey that will allow hospices to add their own questions, but that the core questions will be used for valid

comparisons across hospices because we will define the protocols and guidelines for the implementation of the survey to create an equal implementation process for the survey.

<u>Comment</u>: We received a comment that we cannot regulate payment based on what the living family members think of hospice care because it is not possible to make everyone happy and asking about this experience post death seems odd and could result in a larger percentage of negative responses.

Response: We appreciate this viewpoint. However, the survey itself does not focus on the death. It focuses on the hospice care and the details about the experience of care with the hospice. The survey's purpose is to provide useful information to other caregivers and families who are in the position of comparing hospices for the care of their loved ones.

Comment: We received a comment that there are many family and friends at the time of the death but that they may not be present after the death when the survey goes out. We also received a comment that some hospices will send out multiple surveys to family members who had perceived good experiences, and conversely, will not send out surveys to family members who are mentally ill, or were not involved in the hospice patient's care, even if they were listed as the closest relative. We received a comment that the results may be skewed by the family member's degree of contact with the patient and hospice team.

Response: We appreciate these sensitive comments concerning who will be the survey respondent. We propose to have a uniform standard for the designation of the survey respondent. We propose that the survey respondent will be the person who is listed in the hospice record as the primary caregiver or primary contact person for the hospice patient.

<u>Comment</u>: We received a comment that surveys should not be sent more than two times to families as there is a need not to be too intrusive.

Response: For the field test, we will have one survey mode, called the mixed mode that includes both a mail survey and telephone follow-up for non-respondents. If the survey respondent does not return the mailed questionnaire, then the survey respondent is called and asked to complete the telephone survey instrument. For national implementation of the survey, we will have three modes: mail only, telephone only, and mixed. For the mail only mode, only two surveys are mailed to the sampled person. For the telephone only mode, there will be up to five call attempts to reach the sampled respondent, but once the sampled respondent answers the telephone and speaks with the telephone surveyor, the respondent will only be asked to complete the survey once.

<u>Comment</u>: We received comments that rural hospices will be at a disadvantage paying for the Hospice Experience of Care Survey, and that there should not be a 2 percent reduction since hospices save money for Medicare.

Response: We are requiring the survey for all hospices, to meet the goals of transparency for hospices regardless of their location. We believe that the burden to rural and urban hospices is equal, and we reiterate that small hospices serving 50 or fewer in a given year will be exempt from survey participation if they complete the survey's Participation Exemption Request form for each APU.

<u>Comment</u>: We received a comment asking if CMS would require the survey to be available in other languages, such as Spanish.

Response: Vendors will be required to offer the survey in English and Spanish.

Hospices will be able to administer the survey in additional languages if needed for their patient populations; however, they must use the CMS official translations. We plan to make additional

translations of the survey available as needed. If you would like to request a specific translation, please email CMS at hospicesurvey@cms.hhs.gov.

<u>Comment</u>: We received a comment stating that it is not clear whether hospices are given the full credit for survey participation regardless of the survey results.

Response: We stated in the proposed rule that survey participation is required for the full APU; the data results are not part of the requirements for the APU. The survey requirement is part of the Hospice Quality Reporting Program; this is not a pay for performance program.

<u>Comment</u>: We received a comment stating that their vendor for the FEHC notifies them immediately about negative comments that are received about their hospice. This commenter noted that there is no information in the proposed rule that describes how the comment section of the proposed survey will be used, or available to the hospice paying for survey service.

Response: Hospices will still be able to have this arrangement with their respective vendors in the CMS Hospice Experience of Care Survey.

<u>Comment</u>: We received a comment asking if hospices will be responsible for a certain response rate for the Hospice Experience of Care Survey.

Response: No, hospices will not be responsible for a certain response rate for the Hospice Experience of Care Survey. However, all approved survey vendors must follow the survey administration protocols to implement the survey.

<u>Comment</u>: We received a comment of support for the FEHC survey and questions about why CMS is mandating the new survey in place of the FEHC. We also received a comment that CMS should allow the FEHC to be substituted for the CMS Hospice Survey.

Response: We respect the work that went into the FEHC; however, we cannot allow the FEHC to substitute for the CMS survey. To be useful to the public, Hospice Survey data must be

comparable across hospices. Two different surveys would create inconsistencies among hospices that would not allow for direct comparisons. In addition, the FEHC was designed by and for a private entity. CMS must ensure that no private entity has a preferred relationship with the agency. The CMS survey was developed under the standards of the CAHPS® surveys and will be implemented with the rigorous guidelines of the CAHPS® surveys.

Comment: A commenter stated that the dry run should be 3 months, instead of 1 month.

Response: The requirement for the dry run is 1 month, but hospices are allowed to do 2 or 3 months, in the period of January through March 2015.

<u>Comment</u>: We received a comment that consideration needs to be given to the diverse audiences responding to the survey. Issues related to primary language, socioeconomic status, culture, and health literacy, may impact the completion of the survey and the responses to the survey questions.

Response: We agree with this commenter and will adjust the survey results for respondent mix. We will also be offering multiple translations and different modes of survey administration so hospices can choose what meets their needs the best.

<u>Comment</u>: We received a comment that consideration needs to be given to the smaller agency where one negative survey can skew the data results for that agency.

Response: For other CAHPS® surveys, we have received comments about the comparability of the data for small providers with large providers. In the practice of statistics, it is established that the sample size in absolute numbers is more important than the proportion of the population surveyed. Surveying a sample of 300 will produce the same level of precision whether the sample large or small. The larger the sample, the less the variability is a provider's ratings over time. We will be proposing the required sample sizes for all hospices in next year's

proposed rule. Small agencies will need to conduct census sampling if they do not qualify for the size exemption.

<u>Comment</u>: We received a comment that CMS needs to know what its ultimate goal is of the surveys without losing sight of the goal itself.

Response: The goals of the Hospice Experience of Care Survey are the same as the goals of our other CAHPS® surveys: (1) to produce comparable data on the caregiver's or loved one's' perspectives on care that allow objective and meaningful comparisons between hospices on domains that are important to consumers; (2) to create incentives for hospices to improve their quality of care through public reporting of survey results; and (3) to enhance public accountability in health care by increasing the transparency of the quality of the care provided in return for the public investments. CMS is serious about these three goals for all of our perspectives of care/ CAHPS® surveys, and we intend to never lose sight of their importance.

<u>Comment</u>: We received a comment that the first portion of the survey is nearly identical to HHCAHPS, while the latter portion seems more representative of hospices. This commenter stated that questions regarding goals of care or the patient's plan of care were absent, two areas of particular importance for hospices. This commenter also noted that questions regarding afterhour response to needs were absent, an area known to create much anxiety for patients and families.

Response: We reviewed both surveys side-by-side and disagree with this commenter about the similarity to HHCAHPS. We have some similar questions, but this is because in focus groups and later testing these issues were all raised by our testing participants. Also, we have many questions about care. We also have questions about after-hour response to needs. They are: "While your family member was in hospice care, did you need to contact the hospice team

during evenings weekends or holidays for questions or help with your family member's care?, and "How often did you get the help you needed from the hospice team during evenings, weekends, or holidays?

<u>Comment</u>: We received a comment about transitioning from the current FEHC program to the CMS Hospice Survey.

Response: We do not have any relationship to the FEHC program. Hospices can continue to continue to use the FEHC. However, the FEHC cannot be substituted for the CMS Hospice Experience of Care Survey. Hospices can conduct both surveys under specific conditions that will be detailed in the CMS Hospice Survey Guidelines Manual, which has not been written.

<u>Comment</u>: We received a comment that the survey should meet the quality needs of individual hospices.

Response: We hope that the survey will serve the quality needs of all hospices.

However, hospices may have unique quality needs and hospices will be permitted to add their own additional questions to the standardized survey.

<u>Comment</u>: We received comments that the caregiver of record is not always the best person to receive the survey.

Response: We are aware the caregiver of record may not be the best person to receive the survey. However, because the hospice is likely to have contact information for this person, they are the best person for us to contact.

<u>Comment</u>: We received comments expressing the concern that collecting demographic information from respondents could reduce response, especially from minority populations. In addition, commenters said that asking for this information could raise privacy and confidentiality

concerns. We received a comment suggesting CMS redesign the Hospice Experience of Care Survey so that there were no survey questions about demographic characteristics. The commenter has received feedback that no one likes to answer those kinds of questions.

Response: We ask for demographic information on surveys for two purposes: First, to allow us to make case mix adjustments so that hospices' survey responses can be compared fairly. We have not determined how case mix adjustments will be calculated for this survey, and therefore, need demographic variable to test different case mix adjustment variables. Second, we also need demographic information to allow for research on health care disparities between groups of people, including minorities. All sampling data, which will include these items, will be treated as private and confidential. The approved survey vendors who conduct these surveys will be responsible for maintaining the security, privacy and confidentiality of sampling information and survey results in accordance with HIPAA requirements. Above all, the completion of the survey is voluntary for all persons who receive the survey in the mail, or who are telephoned and are asked to complete the survey on the telephone. Any person who receives the survey, or who is telephoned and is asked to complete the survey, is free not to complete the survey.

<u>Comment</u>: We received a comment that the survey data should be adjusted for length of hospice stay and for the care setting.

Response: We will use the data from the field test to determine if the administrative data (such as length of stay and hospice setting) has an impact on the survey data results.

<u>Comment</u>: We received comments that CMS should not exempt very small rural hospices from the requirements.

Response: Besides the burden to these hospices, there is the issue of privacy to the

respondents. In very small settings, it could be apparent who the survey respondents are. Also, there are sampling and reliability issues because the sample and the data could be very small.

<u>Comment</u>: We received comments stating that it is going to be very difficult for survey respondents to complete the survey if their loved ones changed hospice settings.

<u>Response</u>: At the beginning of the survey, respondents are instructed to reply to the questionnaire as pertaining to the last setting of hospice care.

<u>Comment</u>: We received comments suggesting that CMS add questions to the survey.

The suggested topics for added items include questions specifically relevant to veterans as well as questions about care planning, care goals, and volunteers.

Response: One of the concerns often expressed to us is that the CMS Hospice Experience of Care Survey is too long. We intend to shorten the survey after the field test. In this context, we are reluctant to add still more questions to the core survey instrument. However, we know that it can be important for providers to ask questions that are not on the approved core survey instrument. Hospices will be permitted to add their own questions to the survey, following the required core set of questions.

<u>Comment</u>: We had one comment that suggested the follow-up schedule for the field test of the Hospice Experience of Care Survey was too aggressive and would make family members or friends of the deceased feel harassed.

Response: Our follow-up plan for the field test is very typical for professional mixed-mode surveys. We plan to mail a survey to the sample members. Sample members who have not responded within three weeks will receive follow-up telephone calls. We will make up to a maximum of five telephone calls, at different days and times, in an effort to reach the sample member. If we have not reached the sample member after five attempts, calls will be curtailed.

If the sample member is reached but refuses to complete the survey, no more calls will be made. We will not repeatedly call the sample member and ask for a response.

Summary of Final Rule Changes for the Hospice Experience of Care Survey

As a result of these comments, we are finalizing the requirements as proposed. Hospices must participate in and report data from a dry run for at least 1 month in the first quarter of CY 2015 (January 2015, February 2015, or March 2015) with continuous monthly data collection beginning in April 1, 2015 and continuing through December 31, 2015.

7. Notice Pertaining to Reconsiderations Following APU Determinations

At the conclusion of any given quality data reporting period, we will review the data received from each hospice during that reporting period to determine if the hospice has met the reporting requirements. Hospices that are found to be non-compliant with the reporting requirements set forth for that reporting cycle could receive a reduction in the amount of 2 percentage points to their annual payment update for the upcoming payment year.

We are aware that there may be situations when a hospice has evidence to dispute a finding of non-compliance. We further understand that there may be times when a provider may be prevented from submitting quality data due to the occurrence of extraordinary circumstances beyond their control (for example, natural disasters). It is our goal not to penalize hospice providers in these circumstances or to unduly increase their burden during these times.

Other CMS Quality Reporting Programs, such as Home Health Quality Reporting and Inpatient Quality Reporting, include an opportunity for providers to request a reconsideration pertaining to their APU determinations. We are aware of the potential need for providers to request reconsideration and that we will be making APU determinations for FY 2014 in the coming months. Therefore, to be consistent with other established quality reporting programs,

we used the proposed rule to notify providers of our intent to provide a process that would allow hospices to request reconsiderations pertaining to their FY 2014 and subsequent years' payment determinations.

Specifically, as part of the reconsideration process for hospices beginning with the FY 2014 payment determinations, hospices found to be non-compliant with the reporting requirements during a given reporting cycle would be notified of that finding. The purpose of this notification is to put hospices on notice of the following: (1) that they have been identified as being non-compliant with section 3004 of the Affordable Care Act for the reporting cycle in question; (2) that they would be scheduled to receive a reduction in the amount of 2 percentage points to the annual payment update to the applicable fiscal year; (3) that they may file a request for reconsideration if they believe that the finding of non-compliance is erroneous, or that if they were non-compliant, they have a valid and justifiable excuse for this non-compliance; and, (4) that they must follow a defined process on how to file a request for reconsideration, which would be described in the notification.

Upon the conclusion of our review of each request for reconsideration, we would render a decision. We could reverse our initial finding of non-compliance if: (1) the hospice provides proof of full compliance with the all requirements during the reporting period; or (2) the hospice was not able to comply with requirements during the reporting period, and it provides adequate proof of a valid or justifiable excuse for this non-compliance. We would uphold our initial finding of non-compliance if the hospice could not show any justification for non-compliance.

C. FY 2014 Hospice Wage Index and Rates Update

1. Hospice Wage Index

The hospice wage index is used to adjust payment rates for hospice agencies under the

Medicare program to reflect local differences in area wage levels based on the location where services are furnished. The hospice wage index utilizes the wage adjustment factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustments and our regulations at §418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes by the Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions. We have consistently used the pre-floor, pre-reclassified hospital wage index when deriving the hospice wage index. In our August 4, 2005 FY 2006 Hospice Wage Index final rule (70 FR 45130), we began adopting the revised labor market area definitions as discussed in the OMB Bulletin No. 03-04 (June 6, 2003). That bulletin announced revised definitions for MSAs and the creation of Core-Based Statistical Areas (CBSAs). The bulletin is available online at http://www.whitehouse.gov/omb/bulletins/b03-04.html. In the FY 2006 Hospice Wage Index final rule (70 FR 45139), we implemented a 1-year transition policy using a 50/50 blend of the CBSA-based wage index values and the MSA-based wage index values for FY 2006. The oneyear transition policy ended on September 30, 2006. For the FY 2007 hospice wage index and beyond, we have used CBSAs exclusively to calculate wage index values. OMB has published subsequent bulletins regarding CBSA changes. The OMB bulletins are available at http://www.whitehouse.gov/omb/bulletins/index.html.

When adopting OMB's new labor market designations in FY 2006, we identified some geographic areas where there were no hospitals, and thus, no hospital wage index data, which to base the calculation of the hospice wage index. We also adopted the policy that, for urban labor markets without a hospital from which hospital wage index data could be derived, all of the CBSAs within the state would be used to calculate a statewide urban average pre-floor, pre-

reclassified hospital wage index value to use as a reasonable proxy for these areas in our August 6, 2009 FY 2010 Hospice Wage Index final rule (74 FR 39386). In FY 2014, the only CBSA without a hospital from which hospital wage data could be derived is 25980, Hinesville-Fort Stewart, Georgia.

In our August 31, 2007 FY 2008 Hospice Wage Index final rule (72 FR 50214), we implemented a new methodology to update the hospice wage index for rural areas without a hospital, and thus no hospital wage data. In cases where there was a rural area without rural hospital wage data, we used the average pre-floor, pre-reclassified hospital wage index data from all contiguous CBSAs to represent a reasonable proxy for the rural area. In our August 31, 2007 FY 2008 Hospice Wage Index final rule, we noted that we interpret the term "contiguous" to mean sharing a border (72 FR 50217). Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, our policy of imputing a rural pre-floor, pre-reclassified hospital wage index based on the pre-floor, pre-reclassified hospital wage index (or indices) of CBSAs contiguous to a rural area without a hospital from which hospital wage data could be derived does not recognize the unique circumstances of Puerto Rico. While we have not identified an alternative methodology for imputing a pre-floor, pre-reclassified hospital wage index for rural Puerto Rico, we will continue to evaluate the feasibility of using existing hospital wage data and, possibly, wage data from other sources. For FY 2008 through FY 2013, we have used the most recent pre-floor, pre-reclassified hospital wage index available for Puerto Rico, which is 0.4047. In this final rule, for FY 2014, we will continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047.

For the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule (78 FR

27840), we proposed to use the 2013 pre-floor, pre-reclassified hospital wage index to derive the applicable wage index values for the FY 2014 hospice wage index. We proposed to continue to use the pre-floor, pre-reclassified hospital wage data as a basis to determine the hospice wage index values because hospitals and hospices both compete in the same labor markets, and therefore, experience similar wage-related costs. We believe the use of the pre-floor, prereclassified hospital wage index data as a basis for the hospice wage index results in the appropriate adjustment to the labor portion of the costs. The FY 2014 hospice wage index values presented in this final rule were computed consistent with our pre-floor, pre-reclassified hospital wage index policy (that is, our historical policy of not taking into account Inpatient Prospective Payment System (IPPS) geographic reclassifications in determining payments for hospice). The 2013 pre-floor, pre-reclassified hospital wage index does not reflect OMB's new area delineations, based on the 2010 Census, as outlined in OMB Bulletin 13-01, released on February 28, 2013. Moreover, the final FY 2014 pre-floor, pre-reclassified hospital wage index does not contain OMB's new area delineations because those changes were not published until the IPPS proposed rule was in advanced stages of development (78 FR 27552). CMS intends to propose changes to the FY 2015 hospital wage index based on the newest CBSA changes in the FY 2015 IPPS proposed rule. Therefore, if CMS incorporates OMB's new area delineations, based on the 2010 Census, in the FY 2015 hospital wage index, those changes would also be reflected in the FY 2016 hospice wage index.

We received nine comments on our proposal to use the 2013 pre-floor, pre-reclassified hospital wage index to derive the applicable wage index values for the FY 2014 hospice wage index, which are summarized below.

Comment: Some commenters commented that is difficult to have the hospice wage index

dependent on the hospital wage index due to the lack of data sometimes submitted by the hospital on their cost report data and the added responsibility for the hospice to monitor the hospital wage index. Some commented that the phase out of the BNAF will leave the hospice industry with an exceptionally imprecise and un-validated wage index with large geographic variations that cannot be defended by local wage pressures. Some commenters stated that CMS should actively seek the Congressional authority for granting hospices wage index parity with hospitals until an appropriate alternative wage index approach for hospices and other post-acute providers can be developed. One commenter asked CMS to re-evaluate the CBSA for Montgomery County, Maryland as it is considered a rural area at paid at a lower rate than all the surrounding counties.

Response: The pre-floor, pre-reclassified hospital wage index was adopted in 1998 as the wage index from which the hospice wage index is derived by a committee of CMS (then Health Care Financing Administration) and industry representatives as part of a negotiated rulemaking effort. The Negotiated Rulemaking Committee considered several wage index options: (1)

Continuing with Bureau of Labor Statistics data; (2) using updated hospital wage data; (3) using hospice specific data; and (4) using data from the physician payment system. The Committee determined that the pre-floor, pre-reclassified hospital wage index was the best option for hospice. Each hospice's labor market area is based on definitions of CBSAs issued by the Office of Management and Budget (OMB), not CMS. We note that section 3137(b) of the Affordable Care Act requires CMS to submit to Congress a report that includes a plan to reform the hospital wage index system. The report to Congress outlines the recent history of analysis and proposed reform to the Medicare wage index system. This report was submitted by the Secretary on April 11, 2012. The report can be found at: http://www.cms.gov/Medicare/Medicare-Fee-for-

Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html. The latest information on hospital wage index reform is discussed in the "Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates;" final rule, published August 31, 2012 in the Federal Register (77 FR 53660-53664). We continue to believe that the pre-floor, pre-reclassified hospital wage index, which is updated yearly and is used by many other CMS payment systems, is the most appropriate method available to account for geographic variances in labor costs for hospices. Regarding about the commenters concerns regarding the CBSA classification of Montgomery County, Maryland, it is important to note that the cities and counties which make up CBSAs are not determined by CMS, but instead are established by the Office of Management and Budget (OMB) and have been adopted by Medicare through notice and comment rule making. In our August 4, 2005 FY 2006 Hospice Wage Index final rule (70 FR 45130), we began adopting the revised labor market area definitions as discussed in the OMB Bulletin No. 03-04 (June 6, 2003). In addition, in the FY 2006 Hospice Wage Index final rule (70 FR 45130), we implemented a 1year transition policy using a 50/50 blend of the CBSA-based wage index values and the MSAbased wage index values for FY 2006. The one-year transition policy ended on September 30, 2006. For FY 2007 and beyond, we have used CBSAs exclusively to calculate wage index values. Moreover, we also note that under the hospice payment system, payments are wageadjusted based on the location of the beneficiary.

<u>Final Decision</u>: After carefully considering all of the comments that we received on our proposal to use the 2013 pre-floor, pre-reclassified hospital wage index to derive the applicable wage index values for the FY 2014 hospice wage index, we are finalizing the proposal as discussed in the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule.

2. FY 2014 Hospice Wage Index with an Additional 15 Percent Reduced Budget Neutrality Adjustment Factor (BNAF).

This final rule will update the hospice wage index values for FY 2014 using 2013 prefloor, pre-reclassified hospital wage index. As described in the August 8, 1997 Hospice Wage Index final rule (62 FR 42860), the pre-floor and pre-reclassified hospital wage index is used as the raw wage index for the hospice benefit. These raw wage index values are then subject to either a budget neutrality adjustment or application of the hospice floor to compute the hospice wage index used to determine payments to hospices. Pre-floor, pre-reclassified hospital wage index values below 0.8 are adjusted by either: (1) the hospice budget neutrality adjustment factor (BNAF); or (2) the hospice floor subject to a maximum wage index value of 0.8; whichever results in the greater value.

The BNAF is calculated by computing estimated payments using the most recent, completed year of hospice claims data. The units (days or hours) from those claims are multiplied by the updated hospice payment rates to calculate estimated payments. For the FY 2014 Hospice Wage Index final rule, that means estimating payments for FY 2014 using units (days or hours) from FY 2012 hospice claims data, and applying the FY 2014 hospice payment rates. The FY 2014 hospice wage index values are then applied to the labor portion of the payments. The procedure is repeated using the same units from the claims data and the same payment rates, but using the 1983 Bureau of Labor Statistics (BLS)-based wage index instead of the updated raw pre-floor, pre-reclassified hospital wage index (note that both wage indices include their respective floor adjustments). The total payments are then compared, and the adjustment required to make total payments equal is computed; that adjustment factor is the BNAF.

The August 6, 2009 FY 2010 Hospice Wage Index final rule (74 FR 39384) finalized a provision to phase out the BNAF over 7 years, with a 10 percent reduction in the BNAF in FY 2010, and an additional 15 percent reduction in each of the next 6 years, with complete phase out in FY 2016. Once the BNAF is completely phased out, the hospice floor adjustment would simply consist of increasing any wage index value less than 0.8 by 15 percent, subject to a maximum wage index value of 0.8. Therefore, in accordance with the FY 2010 Hospice Wage final rule (74 FR 39384), the BNAF for FY 2014 will be reduced by an additional 15 percent for a total BNAF reduction of 70 percent (10 percent from FY 2010, an additional 15 percent from FY 2011, an additional 15 percent for FY 2012, an additional 15 percent for FY 2013 and an additional 15 percent in FY 2014).

The unreduced BNAF for FY 2014 is 0.061538 (or 6.1538 percent). A 70 percent reduction to the BNAF is computed to be 0.018461 (or 1.8461 percent). For FY 2014, this is mathematically equivalent to taking 30 percent of the unreduced BNAF value, or multiplying 0.061538 by 0.30, which equals 0.018461 (1.8461 percent). The BNAF of 1.8461 percent reflects a 70 percent reduction in the BNAF. The 70 percent reduced BNAF (1.8461 percent) was applied to the pre-floor, pre-reclassified hospital wage index values of 0.8 or greater.

The 10 percent reduced BNAF for FY 2010 was 0.055598, based on a full BNAF of 0.061775; the additional 15 percent reduced BNAF FY 2011 (for a cumulative reduction of 25 percent) was 0.045422, based on a full BNAF of 0.060562; the additional 15 percent reduced BNAF for FY 2012 (for a cumulative reduction of 40 percent) was 0.035156, based on a full BNAF of 0.058593; the additional 15 percent reduced BNAF for FY 2013 (for a cumulative reduction of 55 percent) was 0.027197, based on a full BNAF of 0.060438; and the additional 15 percent reduced BNAF for FY 2014 (for a cumulative reduction of 70 percent) is 0.018461, based on a

full BNAF of 0.061538.

Hospital wage index values which are less than 0.8 are subject to the hospice floor calculation. For example, if in FY 2013, County A had a pre-floor, pre-reclassified hospital wage index (raw wage index) value of 0.3994, we would perform the following calculations using the budget-neutrality factor (which for this example is an unreduced BNAF of 0.061538, less 70 percent, or 0.018461) and the hospice floor to determine County A's hospice wage index: Pre-floor, pre-reclassified hospital wage index value below 0.8 multiplied by 1+ 70 percent reduced BNAF: (0.3994 x 1.018461 = 0.4068); Pre-floor, pre-reclassified hospital wage index value below 0.8 multiplied by 1 + hospice floor: (0.3994 x 1.15 = 0.4593). Based on these calculations, County A's hospice wage index would be 0.4593.

An Addendum A and Addendum B, with the FY 2014 wage index values for rural and urban areas, will not be published in the **Federal Register**. The FY 2014 wage index values for rural areas and urban areas are available via the internet at:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html. The FY 2014 hospice wage index set forth in this final rule includes the BNAF reduction and will be effective October 1, 2013 through September 30, 2014.

We received nine comments which referenced the BNAF reduction, and are summarized below.

<u>Comment</u>: Several commenters continued to voice opposition to the BNAF reduction and were concerned about the impact of the elimination of BNAF phase-out.

Response: The BNAF phase-out has already been finalized for the remaining years of the phase-out, as described in the FY 2010 Hospice Wage Index final rule (74 FR 39384). However, we are sensitive to the issues raised by commenters, especially the possible effects of the BNAF reduction. Our analysis reveals an overall growth in number of hospices since the start of the

phase-out. We also note that the FY 2014 hospice wage index includes a hospice floor calculation which benefits many rural providers. However, we will continue to monitor for unintended consequences associated with the BNAF phase-out.

3. Hospice Payment Update Percentage

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were to be updated by a factor equal to the market basket index, minus 1 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the market basket percentage for that FY. The Act requires us to use the inpatient hospital market basket to determine the hospice payment rate update. In addition, section 3401(g) of the Affordable Care Act mandates that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage will be annually reduced by changes in economywide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act which is 0.5 percentage point for FY 2014. In addition, section 3401(g) of the Affordable Care Act also mandates that in FY 2013 through FY 2019, the hospice payment update percentage will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act). In FY 2014 Hospice Wage Index and Payment Rate Update proposed rule (78 FR 27841), we proposed 1.8 percent hospice payment update percentage which was based on a 2.5 percent estimated inpatient hospital market basket update for FY 2014 reduced by a 0.4 percentage point productivity adjustment and by 0.3 percentage point as mandated by the Affordable Care Act. The final hospice payment update percentage for FY 2014 is 1.7 percent

and is based on the final inpatient hospital market basket update for FY 2014 of 2.5 percent reduced by a 0.5 percentage point productivity adjustment and by 0.3 percentage point as mandated by the Affordable Care Act. A detailed description of how the inpatient hospital market basket is derived is described in the FY 2014 IPPS Final Rule. Due to the requirements at 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the inpatient hospital market basket update for FY 2014 of 2.5 percent must be reduced by a productivity adjustment as mandated by Affordable Care Act (0.5 percentage point for FY 2014). The inpatient hospital market basket for FY 2014 is reduced further by a 0.3 percentage point, as mandated by the Affordable Care Act. In effect, the final hospice payment update percentage for FY 2014 is 1.7 percent.

The labor portion of the hospice payment rates are as follows: for Routine Home Care, 68.71 percent; for Continuous Home Care, 68.71 percent; for General Inpatient Care, 64.01 percent; and for Respite Care, 54.13 percent. The non-labor portion of the payment rates is as follows: for Routine Home Care, 31.29 percent; for Continuous Home Care, 31.29 percent; for General Inpatient Care, 35.99 percent; and for Respite Care, 45.87 percent.

4. Final FY 2014 Hospice Payment Rates

Historically, the hospice rate update has been published through a separate administrative instruction issued annually in the summer to provide adequate time to implement system change requirements; however, starting in this FY 2014 rule and for subsequent FYs, we proposed in the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule to use rulemaking as the means to finalize hospice payment rates. This change was proposed to be consistent with the rate update process in other Medicare benefits, and would provide rate information to hospices as quickly as, or earlier than, when rates are published in an administrative instruction.

There are four payment categories that are distinguished by the location and intensity of the services provided. The base payments are adjusted for geographic differences in wages by multiplying the labor share, which varies by category, of each base rate by the applicable hospice wage index. A hospice is paid the routine home care rate for each day the beneficiary is enrolled in hospice, unless the hospice provides continuous home care, inpatient respite care, or general inpatient care. Continuous home care is provided during a period of patient crisis to maintain the patient at home, inpatient respite care is short-term care to allow the usual caregiver to rest, and general inpatient care is to treat symptoms that cannot be managed in another setting.

The final FY 2014 payment rates will be the FY 2013 payment rates, increased by 1.7 percent, which is the final hospice payment update percentage for FY 2014 as discussed in section IV.C.3 above. The final FY 2014 hospice payment rates will be effective for care and services furnished on or after October 1, 2013, through September 30, 2014.

Table 7: Final FY 2014 Hospice Payment Rates Updated by the Final Hospice Payment Update Percentage

Code	Description	FY 2013 Payment Rates	Multiply by the FY 2014 final hospice payment update of 1.7 percent	FY 2014 final Payment Rate
651	Routine Home Care	\$153.45	x1.017	\$156.06
652	Continuous Home Care Full Rate = 24 hours of care \$=37.95 hourly rate	\$895.56	x1.017	\$910.78
655	Inpatient Respite Care	\$158.72	x1.017	\$161.42
656	General Inpatient Care	\$682.59	x1.017	\$694.19

The Congress required in sections 1814(i)(5)(A) through (C) of the Act that hospices begin submitting quality data, based on measures to be specified by the Secretary. Beginning in FY 2014, hospices which fail to report quality data will have their market basket update reduced by 2 percentage points. In the August 4, 2011 FY 2012 Hospice Wage Index final rule (76 FR 47320 through 47324), we implemented a Hospice Quality Reporting Program (HQRP) as required by section 3004 of the Affordable Care Act. Hospices were required to begin collecting quality data in October 2012, and submit that quality data in 2013. Hospices failing to report quality data in 2013 will have their market basket update reduced by 2 percentage points in FY 2014.

Table 8: Final FY 2014 Hospice Payment Rates Updated by the Final Hospice Payment Update Percentage for Hospices That DO NOT Submit the Required Quality Data

Code	Description	FY 2013 Payment Rates	Multiply by the FY 2014 hospice payment update percentage of 1.7 percent minus 2 percentage points (-0.2)	FY 2014 Payment Rate
651	Routine Home care	\$153.45	x0.997	\$152.99
652	Continuous Home Care Full Rate= 24 hours of care \$=37.20 hourly rate	\$895.56	x0.997	\$892.87
655	Inpatient Respite Care	\$158.72	x0.997	\$158.24
656	General Inpatient Care	\$682.59	x0.997	\$680.54

A Change Request with the finalized FY 2014 hospice payment rates, a finalized FY 2014 hospice wage index, the FY 2014 PRICER, and the hospice cap amount for the cap year ending October 31, 2013 will continue to be issued in the summer.

We received two comments on our proposal to use rulemaking as the means to finalize hospice payment rates, which are summarized below.

<u>Comment</u>: Commenters were supportive of CMS' proposal to use rulemaking as the means to finalize hospice payment rates followed by a change request with the finalized hospice payment rates, a finalized hospice wage index, the PRICER for FY 2014.

Response: We thank you for your support. We will finalize hospice payment rates as stated in the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule (78 FR 27841).

<u>Comment</u>: We also received several additional comments that expressed concern that hospice industry is being over regulated, while reimbursement is decreasing and examples given include the face-to-face regulation, data collection efforts, and quality initiatives. Several commenters are concerned that these regulations not only increase financial burden for hospice industry but also pull hospices away from patient care and keep hospice providers in the office to

perform administrative duty to comply with regulations. Some commenters described a shortage of staff in some areas of the country, especially small hospices and in rural areas, and stated that the staff travel hours in rural areas to examine the patient, which is a burden itself because of travel distance. Several commenters stated that reimbursement is decreasing because of the continuing rate cuts resulting from the elimination of the budget neutrality adjustment factor, the cuts resulting from the productivity adjustment factor, and further rate reduction resulting from sequestration. A commenter stated that the proposed hospice payment update of 1.8 percent for 2014, coupled with other cuts is devastating.

Response: We appreciate comments regarding sequestration cut, but it is outside the scope of this rule. As stated in FY 2013 Hospice Wage Index notice (77 FR 44245), section 3401(g) of the Affordable Care Act mandates that starting with FY 2013 (and in subsequent FYs), the market basket percentage update under the hospice payment system as described in section 1814(i)(1)(C)(ii)(VII) or section 1814(i)(1)(C)(iii) of the Act will be annually reduced by changes in economy-wide productivity as set out at section 1886(b)(3)(B)(xi)(II) of the Act. We do not have authority to change the application of economy-wide productivity adjustment as it is required by the statute. We are sensitive to concerns about hospices being overregulated and concerns expressed from rural hospices that the additional time and distance required to visit a rural patient adds significantly to their costs. We do not have the authority to change the hospice rates beyond the limits set out in the statute, but will consider the costs of rural providers in the context of broader hospice payment system reform. We will continue to monitor the impact of our regulations for any unintended consequences. As described in the Regulatory Impact Analysis (Section, VI), we note that the overall impact of this final rule is an estimated net increase in Federal payments to hospices of \$160 million, or 1.0 percent, for FY 2014.

<u>Final Decision</u>: As stated in the FY 2014 Hospice Wage Index and Payment Rate Update proposed rule, we proposed to finalize hospice payment rates through rulemaking and we are finalizing this policy as proposed. A change request with the finalized FY 2014 hospice payment rates, a finalized FY 2014 hospice wage index, the FY 2014 PRICER, and the hospice cap year ending October 31, 2013 will continue to be issued in the summer.

D. Update on Hospice Payment Reform and Data Collection

In 2010, the Congress amended section 1814(i)(6) of the Act with section 3132(a) of the Affordable Care Act. The amendment authorized the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and for other purposes. The types of data and information described in the Act would capture resource utilization and other measures of cost, which can be collected on claims, cost reports, and possibly other mechanisms determined to be appropriate. The data collected may be used to revise the methodology for determining the payment rates for routine home care, and other services included in hospice care, no earlier than October 1, 2013 as described in section 1814(i)(6)(D) of the Act. In addition, we are required to consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

The proposed rule contained three subsections which updated the public or discussed different aspects of hospice payment reform; there were no proposals in any of these three subsections.

1. Update on Reform Options

Our hospice contractor, Abt Associates, continues to conduct research and analyses, to identify potential data collection needs, and to research and develop hospice payment model

options. To date, we completed an environmental scan; a draft analytic plan; and convened technical advisory panel meetings under the initial contract with Abt in 2010. We are continuing with these efforts under a contract awarded in September 2011. In June 2012, we convened stakeholder meetings where research findings were presented on potential payment system vulnerabilities; utilization of the Medicare Hospice Benefit, including general inpatient care use during the period the beneficiary is enrolled in hospice care; analysis of hospice cost reports; and the effects of the face-to-face encounter requirement. These and other findings are described in the Abt Hospice Study Technical Report, which is available on the CMS Hospice Center webpage, at http://www.cms.gov/Center/Provider-Type/Hospice-Center.html.

Additionally, we continue to conduct analyses of various payment reform model options under consideration. These models include a U-shaped model of resource use, which MedPAC recommended that we adopt, as originally described in Chapter 6 of its March, 2009 report entitled "Report to the Congress: Medicare Payment Policy" (available online at: http://www.medpac.gov/chapters/Mar09_Ch06.pdf). The report noted that the constancy of the per diem payment over the course of a hospice stay is misaligned with a hospice's costs during the stay. A hospice's costs typically follow a U-shaped curve, with higher costs at the beginning and end of a stay, and lower costs in the middle of the stay. This cost curve reflects hospices' higher service intensity at the time of the patient's admission and the time surrounding the patient's death (MedPAC, page 358). Payment under a U-shaped model would be higher at the beginning and end of a hospice stay and lower in the middle portion of the stay.

Analysis conducted by Abt Associates found that very short hospice stays have a flatter curve than the U-shaped curve seen for longer stays and that average hospice costs are much higher. These short stays are less U-shaped because there is not a lower-cost middle period

between the time of admission and the time of death. As such, we are also considering a tiered approach, with payment tiers based on the length of stay. For example, payment for stays of 5 days or less, which occurred for about 25 percent of hospice beneficiaries in 2011, could be made under a per diem system that accounts for the higher hospice costs, with no variation in the rate based on length of stay as would occur under a U-shaped model. Payment for longer stays, where costs follow more of a U-shape, could be made under a tier based on the U-shaped payment model, where the per diem amount fluctuates depending upon whether the days billed are at the beginning, middle, or end of the stay.

Another option is to analyze whether a short-stay add-on payment, similar to the home health Low Utilization Payment Amount (LUPA) add-on, would improve payment accuracy if we retain the current per diem system. The LUPA add-on is made for home health patients who require four or fewer visits during the 60-day episode. These home health episodes are paid based on the visits actually furnished during the episode. For LUPA episodes that occur as the only episode or the first episode in a sequence of adjacent home health episodes for a given beneficiary, an increased payment is made to account for the front-loading of costs (see http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HomeHlthProspaymt.pdf for more information).

Finally, as we collect more accurate diagnosis data, including data on related conditions, we will also evaluate whether case-mix should play a role in determining payments.

a. Rebasing the Routine Home Care (RHC) Rate

In the proposed rule, we updated our review of the hospice RHC rate, but did not include any proposals to rebase the rate. Rebasing the RHC rate involves using the existing components that make up the rate, and recalculating based on more current data. RHC is the basic level of

care under the Hospice benefit, where a beneficiary receives hospice care, but remains at home. With this level of care, hospice providers are reimbursed per day regardless of the volume or intensity of services provided to a beneficiary on any given day. It is anticipated that there would be days when a beneficiary does not require any services, as well as days when a beneficiary requires several visits from the hospice provider.

When the hospice benefit was created in 1983, the RHC base payment rate was set using nine different components of cost from a relatively small set of hospices (n=26) that were participating in a CMS hospice demonstration, as described in the December 16, 1983 Hospice final rule (48 FR 56008). The nine cost components were: nursing care (\$16.25); home health aide (\$12.74); social services/therapy (\$3.23); home respite (\$1.46); interdisciplinary group (\$2.78); drugs (\$1.18); supplies (\$4.49); equipment (\$1.13); and outpatient hospital therapies (\$2.99). The sum of all the components' costs equaled the base payment rate for RHC as stated in that 1983 hospice final rule. The original RHC rate was set at \$46.25. In addition to RHC, we also established three other levels of care for hospice care from data obtained from the Medicare hospice demonstration project: Continuous Home Care (CHC), Inpatient Respite Care (IRC) and General Inpatient Care (GIP).

It is CMS' intent to ensure that reimbursement rates under the Hospice benefit align as closely as possible with the average costs hospices incur when efficiently providing covered services to beneficiaries. As we continue to gather and analyze more data for payment reform, we have found evidence of a potential misalignment between the current RHC payment rate and the cost of providing RHC. One potential option to address this misalignment could be to rebase the hospice RHC rate, though we did not propose to do so in the proposed rule, so that the cost categories established in the rate reflect the changes in the utilization of hospice services

provided for palliation and management of terminally ill patients. However, we are still evaluating data and did not propose any changes to address the misalignment.

At this time, we do not have the data to support rebasing six of the nine cost components described in the 1983 final rule. Information on the utilization of drugs, supplies, and equipment is not available from hospice claims data, and the corresponding information that is available from cost reports, such as outpatient hospital therapies, is not sufficiently detailed to allow for rebasing. One approach to consider in more closely aligning RHC payments with costs is to rebase the three clinical service components (nursing, home health aide, social services/therapy) that currently comprise 69.7 percent of the RHC rate by calculating the average cost per day, weighted by the number of RHC days, for each of the three components using FY 2011 cost report data matched to FY 2011 claims data. As part of rebasing the RHC rate we would then inflate the 1983 cost per day for each of the six remaining components by a factor of 3.1704, which corresponds to the market basket increases between 1983 and 2011.⁸ We note that our cost report analysis thus far found that drug costs over the years have declined, and the other non-labor components are plateauing. A detailed methodology for rebasing the clinical service components of the RHC rate can be found in the Abt Hospice Study Technical Report which was published shortly after displaying the proposed rule, at http://www.cms.gov/Center/Provider-Type/Hospice-Center.html.

Using the methodology described above, the rebased amount for FY 2011 would be \$130.54 as described in Table 9 below.

⁸ The original RHC rate in 1983 was \$46.25. The FY 2011 rate for RHC was \$146.63. \$146.63/46.25 = 3.1704.

Table 9: Comparison of RHC Rate Cost Components from 1983 to FY 2011

RHC components	1983 Final Rule Cost Per	Inflation	FY 2011 Cost per Day
	Day	Factor	
Nursing Care	\$16.25	N/A	\$56.54
Home Health Aide	\$12.74	N/A	\$19.24
Social Services/Therapy	\$3.23	N/A	\$10.29
Home respite	\$1.46	X 3.1704	\$4.63
Interdisciplinary group	\$2.78	X 3.1704	\$8.81
Drugs	\$1.18	X 3.1704	\$3.74
Supplies	\$4.49	X 3.1704	\$14.23
Equipment	\$1.13	X 3.1704	\$3.58
Outpatient Hospital	\$2.99	X 3.1704	\$9.48
Therapies			
Total	\$46.25		\$130.54

Source: 1983 Final Rule and FY 2011 hospice cost report and claims data.

Note(s): The costs per day for the clinical services components (nursing care, home health aide and social services/therapy) were calculated based on the cost per minute for each discipline using cost report data multiplied by the RHC minutes for each discipline per RHC day from claims data to compute the cost of a discipline per RHC day. The average cost per day across all hospices in our sample was weighted by the number of RHC days. Of the 2,717 FY 2011 hospice cost reports for freestanding and facility-based hospices that were matched to FY 2011 claims data, we excluded: (1) cost reports with period less than 10 months or greater than 14 months; (2) cost reports with missing information or negative reported values for total costs or payments; (3) providers in the highest and lowest percentile (1% and 99%) in costs per days across all levels of care; (4) the top and bottom 5% of provider margin; and (5) providers were excluded if the log payment to cost ratio was greater than the 90th or less than the 10th percentile of this value across all providers plus or minus 1.5 times the range between the 10th and 90th percentiles of this log ratio. The number of hospices remaining in our sample was 2,140 representing 73.1 percent of RHC days in 2011.

For example, if we were to apply the rebased amounts for the clinical services components of RHC to FY 2014, we would inflate the FY 2011 rebased amount to FY 2013 levels. We first inflated the FY 2011 rebased rate by full hospital market basket of 3.0 percent for FY 2012. The FY 2012 rebased rate would be \$134.46 (\$130.54 x 1.03=\$134.46). We then inflated the FY 2012 rebased rate by full hospital market basket of 2.6 percent for FY 2013. The FY 2013 rebased rate would be \$137.96 (\$134.46 x 1.026=\$137.96). Finally, we inflated the rebased FY 2013 rate (\$137.96) by applying the proposed hospice payment update percentage of 1.8 percent to calculate a FY 2014 rebased RHC rate. Therefore, the FY 2014 rebased rate would be \$140.44, a 10.1 percent reduction in the FY 2014 proposed RHC payment rate of \$156.21, or an estimated reduction in payments to hospices of \$1.6 billion in FY 2014. Rebasing

the clinical service components of the RHC payment is one of several approaches to hospice payment reform that CMS could consider for revising the RHC payment rate. As outlined in the Affordable Care Act, hospice payment reform must be done in a budget neutral manner. As rebasing is considered part of hospice payment reform, any savings achieved through the reduction of the RHC rate would need to be redistributed in a budget neutral manner.

b. Site of Service Adjustment for Hospice Patients in Nursing Facilities.

As part of future hospice payment reform, we are considering an OIG recommendation to reduce payments to Medicare hospices for beneficiaries in nursing facilities who are receiving hospice care. The OIG's July 2011 report entitled "Medicare Hospices that Focus on Nursing Facility Residents," (available at https://oig.hhs.gov/oei/reports/oei-02-10-00070.pdf) studied hospice patients in nursing facilities. This report noted the growth of hospice services provided to beneficiaries in nursing facilities, and discussed hospices that have a high percentage of their beneficiaries in nursing facilities. The OIG's report noted that the current payment structure provides incentives for hospices to seek out beneficiaries in nursing facilities, as these beneficiaries often receive longer but less complex care. The OIG noted that unlike private homes, nursing facilities are staffed with professional caregivers and are often paid by third-party payers, such as Medicaid. These facilities are required to provide personal care services, which are similar to hospice aide services that are paid for under the hospice benefit. To lessen this incentive, the OIG recommended that we reduce Medicare payments for hospice care provided in nursing facilities.

In addition, the March 2012 Medicare Payment Advisory Commission (MedPAC) report entitled "Report to Congress: Medicare Payment Policy" noted that hospices with a higher share of their patients in nursing facilities have margins as high as 13.8 percent (pages 302 and 303).

MedPAC attributed these higher margins to possible efficiencies in the nursing home setting (multiple patients in a single setting, reduced driving time and mileage), and to reduced workload due to an overlap in aide services and supplies provided by the nursing facility.

In response to both MedPAC's and OIG's concerns about possible duplication of aide services provided both by the hospice and the nursing facility, in the proposed rule we discussed an analysis of the number and length of aide visits per day using 2011 hospice claims data.

Table 10 below describes the number and length of aide visits for RHC beneficiaries at home (including patients in an assisted living facility) compared to RHC beneficiaries in a long term care nursing facility (NF) or skilled nursing facility (SNF).

Table 10. Hospice Routine Home Care Aide Services, CY 2011

•	Sites of Service		Difference	
	Home Q5001/2	NF/SNF Q5003/4	NF/SNF - Home	%
Number of beneficiaries	769,640	302,004	(467,636)	
Total days	58,637,171	22,946,972	(35,690,199)	
Total visits	16,625,635	8,501,366	(8,124,269)	
Total minutes	1,223,254,095	584,825,520	(638,428,575)	
Visits per beneficiary	21.6	28.1	6.5	30.3%
Minutes per visit	73.6	68.8	(4.8)	6.5%
Total visits / day	0.28	0.37	0.09	30.7%
Total minutes / day	20.86	25.49	4.62	22.2%

Source: Abt Associates Hospice Claims Data File, CY 2011.

Table 10 demonstrates that hospice patients in a NF/SNF receive more visits than patients at home, though the length of those visits is shorter. Average minutes per day shows that RHC patients in a NF/SNF had hospice aide services of longer duration (25.49 minutes) than RHC patients at home (20.86 minutes). The Medicare Conditions of Participation (CoPs) require that hospices provide services at the same level and to the same extent as those services would be provided if the NF/SNF resident were in his or her home. Hospices provide aide services to

beneficiaries at home depending on the beneficiaries' needs. It seems reasonable to expect that a beneficiary who has a paid caregiver (that is, a NF/SNF aide) does not need as many services from the hospice aide, because those services are being provided by the paid caregiver. As described in the June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32095), "[h]ospice care is meant to supplement the care provided by the patient's caregiver." Given the presence of the paid caregiver in the NF/SNF, we would expect that on average, there would be fewer hospice aide services provided to hospice patients in a NF/SNF than to hospice patients at home.

It is not clear why hospice patients in nursing facilities are receiving more minutes per day of aide services than hospice patients at home. We used regression analysis to control for age, gender, diagnosis, length of stay, and provider characteristics (ownership status, base, size, age of hospice, geographic location) when analyzing the visit data. However, we still found that significantly more aide services were provided to NF/SNF patients than to patients at home, even after controlling for patient and provider characteristics.

The June 5, 2008 Hospice Conditions of Participation final rule (73 FR 32088) preamble details the requirements related to aide services provided to hospice patients residing in a nursing facility. These requirements can also be found at §418.112(c)(4) through (5). The CoPs require a written agreement between the hospice and NF/SNF, which specifies that the NF/SNF should continue to provide the aide services that are provided prior to the hospice election, to meet the patient's needs at that same level of care as if the patient were at home. These services include providing 24 hour room and board care, meeting the patient's personal care needs, and to the degree permitted by State law, administering medications or therapies. There should be no reduction of NF/SNF aide services to a patient in anticipation of a future hospice election, or

once the patient (or his/her representative) elects the hospice benefit. As such, hospice patients in nursing facilities should have much, if not most, of their need for aide services provided by the facility's aide. As stated previously, we would expect that, on average, the hospice aide would be providing fewer services to nursing facility patients than to patients at home.

Table 10 suggests that the hospice aide may be replacing the facility aide, rather than supplementing or augmenting the care of the facility aide. Or, as the OIG and MedPAC identified, there could be an overlap in aide services when a hospice beneficiary is in a NF/SNF. It would not be appropriate for the Medicare Hospice Benefit to subsidize the nursing home benefit by providing aide services that the facility aide should provide. Section 1862(a)(1)(C) of the Social Security Act (the Act) forbids payment for any items or services which are not reasonable and necessary for the palliation and management of the terminal illness. Services which are not needed, or which are duplicative of those to be provided by the facility aide, would not be reasonable and necessary.

In the proposed rule, we did not propose to make a site of service adjustment to reduce payments for RHC patients in a nursing facility. Any reform option considering reduced payments for RHC care provided to hospice patients in a NF or SNF should not result in a reduction in the services that hospice patients in NFs or SNFs receive, but would instead be a shifting of who provides those aide services; some of the services currently provided by the hospice aide would be provided by the facility aide as expected. As such, we do not expect that the quality of care to hospice patients in a NF/SNF would be diminished. If such a policy were to be finalized and implemented, it would be made in a budget neutral manner as required by the Affordable Care Act. In addition, we would monitor for any unintended consequences.

2. Reform Research Findings

The proposed rule also included a discussion of a number of analyses we conducted to better understand hospice utilization and trends, to identify vulnerabilities in the payment system, and to develop and test models that would more accurately match hospice resource use with Medicare payments. We posted the Abt Hospice Study Technical Report on hospice payment reform on our hospice center webpage, located at: http://www.cms.gov/Center/Provider-Type/Hospice-Center.html. The report summarizes research findings related to resource use and payment system vulnerabilities.

The report also includes a discussion of hospice cost report analyses. Overall, the total cost per election period has not significantly increased from 2007 to 2010, in real dollars. Inpatient costs constitute about 14 percent of hospice costs across freestanding hospice providers that reported inpatient costs. About one-third of providers reported no inpatient costs. It appeared that some providers with no inpatient costs were substituting continuous home care (CHC) for GIP, based on analysis of the proportion of CHC days. Visiting services (for example, direct labor costs for nurses, aides, social workers, counselors, and therapists) account for about two-thirds of hospice costs, and have trended upward from 2004 to 2010. Nursing care, hospice aides, and medical social services comprise 90 percent of visiting service costs.

Other hospice service costs include non-labor costs such as drugs, durable medical equipment (DME), supplies, imaging, patient transportation, and outpatient services. These types of services represent about 20 to 25 percent of total hospice costs. Drugs, DME, and supplies account for 90 percent of these other hospice services costs. Drug costs have trended downward over time, while medical supply costs have remained steady. Finally, in examining non-reimbursable costs, we found that 26 percent of providers in 2010 showed no bereavement costs on their cost report, even though bereavement services are required by statute; it is unclear

if bereavement services were not provided or if bereavement costs were not correctly reported.

The report also describes an analysis of GIP utilization. In 2010 through 2011, a quarter of all hospice beneficiaries had at least one GIP stay, with a quarter of those stays associated with cancer diagnoses. While most GIP stays were 2 days long, the average GIP length of stay was 5.66 days, reflecting a small number of extremely long GIP stays. Sixty-five percent of GIP stays were provided in a hospice inpatient unit. Almost 80 percent of hospices provided at least one GIP day in 2010 through 2011. Hospices that provided GIP tended to be older and larger.

The Abt Hospice Study Technical Report also provides descriptive statistics for all beneficiaries and for 3 major sites of routine home care services. It includes visit data findings, including visits per day, visits per beneficiary, minutes per day, and minutes per beneficiary for key disciplines reported on hospice claims. Additionally, there are several figures which depict the U-shaped curve for key personnel by length of stay. The curves show that resource use tends to follow a U-shaped curve, but one which is higher at the beginning rather than at the end of the hospice stay. There was little evidence that strong differences in the U-shape exist across most subgroups (for example, freestanding vs. provider-based, ownership status, patient diagnosis).

For more detailed information on these findings, and a description of the methods used, see the Abt Hospice Study Technical Report, which is posted on the hospice center webpage (http://www.cms.gov/Center/Provider-Type/Hospice-Center.html). We have also posted a review of pertinent hospice literature as of December 2012 on the hospice center webpage. This should be considered an evolving document, as Abt Associates updates the review periodically. We encourage interested stakeholders to review this update on our progress. We will continue to collaborate with other federal experts regarding hospice payment reform research efforts and to update stakeholders on our progress on hospice payment reform.

3. Additional Data Collection

Over the past several years, MedPAC, the Government Accountability Office (GAO), and the HHS Office of Inspector General (OIG) have also recommended that we collect more comprehensive data in order to better understand the utilization of the Medicare Hospice Benefit. In the proposed rule, we noted that in December 2012 we posted a document to our Hospice Center webpage (http://www.cms.gov/Center/Provider-Type/Hospice-Center.html) describing additional data collection which we are considering, and noting that cost report revisions are forthcoming. We received 65 comments about the claims data collection items under consideration, which are briefly summarized below.

- Line item visit data, including length of visit in 15-minute increments, for hospice chaplains and counselors providing care to hospice beneficiaries. Commenters were supportive, but suggested we include phone calls by chaplains and counselors, and allow reporting of chaplain time spent officiating or attending beneficiary funerals, as this is part of their service to families. A few suggested that we have a separate category for Bereavement Counseling to acknowledge this requirement even if it is not subject to reimbursement. Several suggested we define "other counselors."
- Line item visit data, including length of visits in 15-minute increments, for hospice staff providing care to hospice patients receiving GIP in a hospital or nursing facility, but not for hospice patients receiving GIP in a hospice facility. Our suggestion to collect GIP visit data did not include visits by non-hospice staff, and was focused on patients in a hospital or nursing facility only. Therefore, GIP visits to hospice patients in hospice inpatient facilities continue to be reported as weekly totals, without including the length of visits. Commenters were generally supportive, provided the visits were for hospice staff only. Several comments

noted that this would be no more difficult than what already occurs when recording visits to patients' homes.

- The National Provider Identifier (NPI) of facilities where hospice patients are receiving care. Most commenters noted that it would not be difficult to get this information and enter it into their systems. A few commenters noted that sometimes patients are in more than one facility type during a claim period, but that there is only space for one NPI on the claim.
- Post-mortem visits on the calendar day of death. Commenters suggested we collect visit data for various timeframes after the time of death, rather than the calendar day of death, since many deaths occur late at night. They suggested we clarify what we mean by time of death (time death actually occurs, or time the death is pronounced). Several commenters suggested we gather post-mortem visit data regardless of level of care or site of service.
- Any durable medical equipment (DME) provided by the hospice. Some commenters indicated that this would be difficult to collect and record on claims. Many indicated that DME suppliers bill them monthly, and waiting for the DME invoice would cause a delay in submission of their claims. They also noted that it would take a great deal of lead time to set this up with suppliers and software vendors to track DME at the patient level. A few suggested that we use aggregate data on DME costs from the cost reports instead.
- Non-routine supplies provided by the hospice. Most commenters indicated that this would be difficult to collect and record on claims. A number of commenters wrote that their software does not accommodate such reporting, and that it would create an additional burden on clinical staff to track these items. Several mentioned that it would take some lead time to modify existing systems to enable hospices to track and report this information accurately. A few suggested we use aggregate data on non-routine supplies from the cost reports instead.

• Drugs (injectable, non-injectable, and over-the-counter) provided by the hospice. Most commenters indicated that this would be difficult to collect and record on claims. Several asked if injectable drugs include infusion pumps, which is considered DME. Several commenters noted that the hospice staff person is not always the person administering drugs, making tracking more complicated; they suggested focusing on the fills, rather than drugs administered. Some wrote that hospices get their drugs from multiple pharmacies, making reporting more difficult due to inconsistencies in pharmacy billing. Others wrote that their data systems are not able to track drugs by patient, and suggested that we use aggregate data from the cost reports instead. Some noted that they purchase some drugs in larger quantities, making reporting at the patient level more complicated. A few noted that this could be done, but said that hospices would need lead time to prepare systems to track and report at the patient level. One suggested that we specify what cost structure drug charges should be based upon, such as average wholesale price plus a percentage.

In summary, commenters were largely supportive of our suggestions to collect additional visit and NPI data on claims. Many suggested collecting data on DME, supplies, and drugs from the cost reports, rather than at the patient level. Several commenters reminded us that their primary focus is patient care, and were concerned about the cost of such data collection. We appreciate the comments submitted, and will consider this input as we move forward towards implementing any new data collection for hospices. We issued Change Request 8358 on Friday, July 26, 2013 detailing the new data collection requirements.

Section 3132(a)(1)(C) of the Affordable Care Act also authorizes us to collect more data on hospice cost reports. The revisions to the hospice cost report and its associated instructions are described in detail in a revision to the information collection request currently approved

under OMB control number 0938-0758. As required by the Paperwork Reduction Act, we published the both 60-day and 30-day notices with comment periods in the **Federal Register** on April 29, 2013 (78 FR 25089).

The proposed rule did not solicit comments on our hospice payment reform updates and discussions, but we received 54 comments on this section. We thank the commenters for their input and we will consider the comments received as we move forward with hospice payment reform.

E. Technical and Clarifying Regulations Text Change

We proposed to incorporate the following technical change to correct an erroneous cross reference in our regulations text.

Administrative Appeals (§418.311)

A hospice that does not believe its payments have been properly determined may request a review from the intermediary or from the Provider Reimbursement Review Board (PRRB), depending on the amount in controversy. Section 418.311 details the procedures for appealing a payment decision and also refers to 42 CFR part 405, subpart R. The rationale for this appeals process was explained in the August 22, 1983 Hospice proposed rule (48 FR 38146) and finalized in the December 16, 1983 Hospice final rule (48 FR 56008). Hospices are permitted to appeal computation of the payment limit or the amount due to the hospice to the PRRB if the amount in controversy is \$10,000 or more.

We made a technical correction in §418.311 to correct an erroneous reference to §405.1874. The published reference to §405.1874 does not exist and was a typographic error. We are correcting this error by changing the referenced §405.1874 to §405.1875-- Administrator review. Section 405.1875 allows for the Administrator, at his or her discretion, to immediately

review any decision of the Board as described in the August 22, 1983 proposed and December 16, 1983 final rules (48 FR 38159, and 48 FR 56019, respectively).

We received no comments on this proposed technical correction, and are implementing the correction as proposed.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
 - The accuracy of our estimate of the information collection burden.
 - The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for this section of this document that contains information collection requirements (ICRs).

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Under section 1814(i)(5)(D)(iii) of the Act, the Secretary must publish selected measures that will be applicable with respect to FY 2014 not

later than October 1, 2012. In implementing the Hospice quality reporting program, we seek to collect measure information with as little burden to the providers as possible and which reflects the full spectrum of quality performance.

We proposed and will implement a Hospice Experience of Care Survey to reflect the patients' families' and friends' perspectives of care in hospices. The 60-day notice for the field test of the survey was published on April 4, 2013 (78 FR 20323) under CMS-10475 (OCN 0938-New). While we set out the requirements and burden estimates for the field study, it is too early to set out the requirements and burden estimates for the national implementation of the survey. We anticipate having the final survey instrument in 2014 and setting out the collection of information requirements and burden estimates in the proposed rule for CY 2015. We will implement the survey in 2015.

In this final rule we are requiring implementation of a hospice patient-level item set to be used by all hospices to collect and submit standardized data on each patient admitted to hospice. This Hospice Item Set will be used to support the standardized collection of the requisite data elements to calculate quality measures. Hospices will be required to complete and submit an admission HIS and a discharge HIS on all patients admitted to hospice starting July 1, 2014 for FY 2016 APU determination. The admission and discharge HIS will collect the standardized data elements needed to calculate 7 NOF endorsed measures for hospice.

Using 2011 Medicare claims data we have estimated that there will be approximately 1,089,719 admissions across all hospices per year and therefore, we expect that there should be 1,089,719 Hospice Item Sets (consisting of one admission and one discharge item set per patient), submitted across all hospices yearly. There were 3,742 certified hospices in the U.S. as of October 1, 2012; we estimate that each individual hospice will submit on average 291 Hospice

Item Sets annually or 24 Hospice Items Sets per month.

The Hospice Item Set consists of both an admission and a discharge data collection. As noted above, we estimate that there will be 1,089,719 hospice admissions across all hospices per year. Therefore, we expect there to be 2,179,438 Hospice Item Set submissions, (both admission and discharge data) submitted across all hospices annually or 181,620 across all hospices monthly. We further estimate that there will be 582 Hospice Item Set submissions by each hospice annually or 49 submissions monthly.

For the Admission Hospice Item Set, we estimate that it will take 14 minutes of time by a clinician such as a Registered Nurse at an hourly wage of \$33.23 to abstract data for Admission Hospice Item Set. This will cost the hospice approximately \$7.75 for each admission assessment. We further estimate that it will take 5 minutes of time by clerical or administrative staff person such as a medical data entry clerk or medical secretary at an hourly wage of \$15.59 to upload the Hospice Item Set data into the CMS system. This will cost the hospice approximately \$1.30 per assessment. For the Discharge Hospice Item Set, we estimate that it will take 5 minutes of time by a clinician such as a nurse at an hourly wage of \$33.23 to abstract data for Discharge Hospice Item Set. This will cost the hospice approximately \$2.77. We further estimate that it will take 5 minutes of time by clerical or administrative staff such as a medical data entry clerk or medical secretary at an hourly wage of \$15.59 to upload data into the CMS system. This will cost the hospice approximately \$1.30.

We estimate that the total nursing time required for completion of both the admission and

 $^{^9}$ 14 minutes of time by a Registered Nurse at \$33.23 / 60 minutes per hour = \$0.56; \$0.56 per one minute x 5 minutes = \$7.75

 $^{^{10}}$ 5 minutes of time by a Medical Data Entry Clerk at \$15.59 / 60 minutes per hour = \$0.265; \$0.265 per one minute x 5 minutes = \$1.30

discharge assessments is 19 minutes at a rate of \$33.23 per hour. The annualized cost across all Hospices for the nursing/clinical time required to complete both the admission and discharge Hospice Item sets is estimated to be \$11,458,528 and the cost to each individual Hospice is estimated to be \$3,062.14. The estimated time burden to hospices for a medical data entry clerk to complete the admission and discharge Hospice Item Set assessments is 10 minutes at a rate of \$15.59 per hour. The cost for completion of the both the admission and discharge Hospice Item sets by a medical data entry clerk is estimated to be \$2,829,401 across all Hospices and \$756.12 to each Hospice.

The total combined time burden for completion of the Admission and Discharge Hospice Data Item Sets is estimated to be 29 minutes. The total annualized cost across all hospices is estimated to be \$14,287,929. For each individual hospice, this annualized cost is estimated to be \$3,818.26. The estimated cost for each individual Hospice Item Set submission is \$13.11.

Comment: We received several comments indicating concern about general burden that would be associated with implementing and using the HIS. Commenters stated hospices will have to conduct training among staff to implement and use the HIS, in addition to staff time that will be required to complete and submit the HIS. Commenters also stated that implementing the HIS will require modifications to clinical documentation processes. Some commenters expressed concerns that implementing the HIS will concurrently entail both implementation of a new data collection tool and implementation of new quality measures. No commenters stated that these burdens were great enough to consider not implementing the HIS for use in the HQRP.

Response: We recognize these activities and efforts will be required to implement and use the HIS as part of the quality reporting program. We agree that it is important for Hospices to learn about and understand the new HIS and we plan to provide hospices with training

resources to facilitate implementation of the HIS. We further acknowledge that specific training costs were not identified in the proposed rule because calculating the training burden is outside the scope of the information collection requirements.

<u>Comment</u>: A few commenters expressed concern that the estimated 29 minutes to complete and upload the admission and discharge HIS was underestimated. One commenter said that the estimated 14 minutes for a staff member to extract data for the Admission HIS and 5 minutes for the Discharge HIS seemed accurate, another commenter indicated that, based on their experiences with the Home Health OASIS, they felt the HIS would take longer than the estimated time.

Response: Burden estimates for completing the HIS data items were based on the HIS pilot test. The HIS is a set of data elements that can be used to calculate 7 NQF endorsed quality measures. The HIS is not a patient assessment that would be administered to the patient and/or family or caregivers during the initial assessment visits; therefore, it cannot be compared to the OASIS instrument. As the HIS is not a true patient assessment, the estimated burden of 14 and 5 minutes do not include the time a clinician would spend assessing the patient. The time estimates are intended to reflect the time it would take hospice staff to complete and submit the HIS, irrespective of clinical activities to collect initial assessment data. The HIS pilot demonstrated that hospices use varying patient assessment forms during the initial patient assessment; all hospices were able to crosswalk items from their hospice's patient assessment forms to the HIS data elements, and complete the HIS items. Therefore, the HIS did not add new data collection efforts to the hospice's customary patient initial assessment.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule follows §418.306(c), which requires annual issuance, in the **Federal Register**, of the hospice wage index based on the most current available CMS hospital wage data. This rule finalizes hospice payment rates for FY 2014. In addition, this final rule provides background on hospice care, clarifies diagnosis coding on hospice claims, updates the public on the status of hospice payment reform, finalizes a technical and clarifying regulatory text change, and finalizes changes to the hospice quality reporting program.

B. Overall Impact

The overall impact of this final rule is an estimated net increase in Federal payments to hospices of \$160 million, or 1.0 percent, for FY 2014. This estimated impact on hospices is a result of the final hospice payment update percentage for FY 2014 of 1.7 percent and changes to the FY 2014 hospice wage index, including a reduction to the BNAF by an additional 15 percent, for a total BNAF reduction of 70 percent (10 percent in FY 2010, and 15 percent per year for FY 2011 through FY 2014). A 70 percent reduced BNAF is computed to be 0.018461 (or 1.8461 percent). The BNAF reduction is part of a 7-year BNAF phase-out that was finalized in the August 6, 2009 FY 2010 Hospice Wage Index final rule (74 FR 39384), and is not a policy change.

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104-4), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule has been designated as economically significant under section 3(f)(1)of Executive Order 12866 and thus a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis (RIA) that to the best of our ability presents the costs and benefits of the rulemaking. Also, the rule has been reviewed by OMB.

2. Detailed Economic Analysis

This final rule sets forth updates to the FY 2013 hospice payment rates. The impact analysis of this final rule presents the estimated expenditure effects of policy changes finalized in this rule. Certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon hospices.

Table 11 represents how hospice revenues are likely to be affected by the policy changes finalized in this rule. In column 1 of Table 11, we indicate the number of hospices included in our analysis as of December 31, 2012, which had also filed claims in FY 2012. In column 2, we indicate the number of routine home care days that were included in our analysis, although the

analysis was performed on all types of hospice care. Column 3 shows the percentage change in estimated Medicare payments for FY 2014 due to the effects of the updated wage data only, compared with estimated FY 2013 payments. The effect of the updated wage data can vary from region to region depending on the fluctuations in the wage index values of the pre-floor, pre-reclassified hospital wage index. Column 4 shows the percentage change in estimated hospice payments from FY 2013 to FY 2014 due to the combined effects of using the updated wage data and reducing the BNAF by an additional 15 percent. Column 5 shows the percentage change in estimated hospice payments from FY 2013 to FY 2014 due to the combined effects of using updated wage data, an additional 15 percent BNAF reduction, and the final 1.7 percent hospice payment update percentage. Taking into account the 1.7 percent final hospice payment update percentage (+\$280 million), the use of updated wage index data (\$-20 million), and the additional 15 percent reduction in the BNAF (\$-100 million), hospice payments will increase by an estimated \$160 (\$280 million - \$20 million -\$100 million = \$160 million) or 1.0 percent in FY 2014.

The impact of changes in this final rule has been analyzed according to the type of hospice, geographic location, type of ownership, hospice base, and size. Table 11 categorizes hospices by various geographic and hospice characteristics. The first row of data displays the aggregate result of the impact for all Medicare-certified hospices. The second and third rows of the table categorize hospices according to their geographic location (urban and rural). Our analysis indicated that there are 2,594 hospices located in urban areas and 975 hospices located in rural areas. The next two row groupings in the table indicate the number of hospices by census region, also broken down by urban and rural hospices. The next grouping shows the impact on hospices based on the size of the hospice's program. We determined that the majority

of hospice payments are made at the routine home care rate. Therefore, we based the size of each individual hospice's program on the number of routine home care days provided in FY 2012. The next grouping shows the impact on hospices by type of ownership. The final grouping shows the impact on hospices defined by whether they are provider-based or freestanding.

Column 5 of Table 11 shows the combined effects of the updated wage data, the additional 15 percent BNAF reduction, and the final 1.7 percent hospice payment update percentage on estimated FY 2014 payments as compared to estimated FY 2013 payments. Overall, hospices are anticipated to experience a 1.0 percent increase in payment, with urban hospices anticipated to experience a 1.0 percent increase in payments, and rural hospices anticipated to experience 1.1 percent increase in payments. Urban hospices are anticipated to experience an increase in estimated payments in every region, ranging from 0.3 percent in the Mountain region to 2.2 percent in New England. Rural hospices in every region but one are estimated to see an increase in payments ranging from 0.4 percent in New England to 1.7 percent in the East South Central and Outlying region. The Pacific region is estimated to see a decrease in payments of 1.2 percent, largely due to fluctuations in the updated hospital wage index data used to create the FY 2014 hospice wage index. Hospital wages in the Pacific region declined compared to the previous year, which led to the decrease in the hospital wage index values, and which thus affected the FY 2014 hospice wage index values.

Column 5 of Table 11 also shows an estimated payment increase by hospice base and hospice size. Payments to hospices in FY 2014 are estimated to increase by 1.4 percent for HHA-based hospices, 1.1 percent for hospital-based hospices, 1.0 percent for SNF-based hospices, and by 0.9 percent for freestanding hospices. Payments to small hospices (less than 3,500 RHC

days) in FY 2014 are estimated to increase by 0.8 percent, whereas payments to large hospices (more than 20,000 RHC days) in FY 2014 are estimated to increase by 1.0 percent.

TABLE 11: Anticipated Impact on Medicare Hospice Payments in FY 2014 in Updating the Pre-floor, Pre-Reclassified Hospital Wage Index Data, Reducing the Budget Neutrality Adjustment Factor (BNAF) by an Additional 15 Percent (for a Total BNAF Reduction of 70 Percent) and Applying a 1.7 Percent Hospice Payment Update Percentage

	Number of Hospices (1)	Number of Routine Home Care Days in Thousands (2)	Percent Change in Hospice Payments due to the Wage Index Update (3)	Percent Change in Hospice Payments due to Wage Index Update, additional 15% Reduction in Budget Neutrality Adjustment (4)	Percent Change in Hospice Payments due to Wage Index Update, additional 15% Reduction in Budget Neutrality Adjustment and Hospice Payment Percentage Update (5)
ALL HOSPICES	3,569	62,945	-0.1%	-0.7%	1.0%
URBAN HOSPICES	2,594	55,101	-0.1%	-0.7%	1.0%
RURAL HOSPICES	975	7,844	-0.2%	-0.6%	1.1%
BY REGION – URBAN:					
NEW ENGLAND	129	1,472	1.1%	0.5%	2.2%
MIDDLE ATLANTIC	249	5,702	0.0%	-0.6%	1.1%
SOUTH ATLANTIC	378	13,173	-0.7%	-1.3%	0.4%
EAST NORTH CENTRAL	338	7,224	0.0%	-0.6%	1.1%
EAST SOUTH CENTRAL	155	3,278	-0.5%	-1.0%	0.7%
WEST NORTH CENTRAL	197	2,494	0.4%	-0.2%	1.5%
WEST SOUTH CENTRAL	517	6,622	-0.4%	-1.0%	0.7%
MOUNTAIN	263	5,698	-0.8%	-1.4%	0.3%
PACIFIC	333	8,141	0.9%	0.2%	1.9%
OUTLYING	35	1,296	0.3%	0.3%	2.0%
BY REGION – RURAL:					
NEW ENGLAND	24	195	-0.7%	-1.3%	0.4%
MIDDLE ATLANTIC	43	439	-0.1%	-0.7%	1.0%
SOUTH ATLANTIC	135	1,918	-0.3%	-0.7%	1.0%
EAST NORTH CENTRAL	138	1,154	0.4%	-0.2%	1.5%
EAST SOUTH CENTRAL	134	1,529	0.1%	0.0%	1.7%
WEST NORTH CENTRAL	182	604	-0.8%	-1.2%	0.5%
WEST SOUTH CENTRAL	176	977	-0.1%	-0.2%	1.5%
MOUNTAIN	95	568	0.4%	-0.1%	1.6%
PACIFIC	47	445	-2.2%	-2.8%	-1.2%
OUTLYING	1	15	0.0%	0.0%	1.7%
BY SIZE/DAYS:					
0- 3499 DAYS (small)	841	1,373	-0.3%	-0.8%	0.8%
3500–19,999 DAYS (medium)	1815	17,403	-0.2%	-0.7%	1.0%
20,000+ DAYS (large)	913	44,168	-0.1%	-0.7%	1.0%
TYPE OF OWNERSHIP:					
VOLUNTARY	1080	23,296	0.0%	-0.5%	1.1%
PROPRIETARY	2002	32,992	-0.3%	-0.9%	0.8%

GOVERNMENT	487	6,656	-0.1%	-0.7%	1.0%
HOSPICE BASE:					
FREESTANDING	2569	50,665	-0.2%	-0.8%	0.9%
HOME HEALTH AGENCY	522	7,728	0.3%	-0.3%	1.4%
HOSPITAL	458	4,430	0.0%	-0.6%	1.1%
SKILLED NURSING FACILITY	20	122	0.0%	-0.7%	1.0%

Source: Provider data as of December 31, 2012 for hospices with claims filed in FY 2012 (Based on the 2012 standard analytic file (SAF).

Note(s): The final 1.7 percent hospice payment update percentage for FY 2014 is based on an estimated 2.5 percent inpatient hospital market basket update, reduced by a 0.5 percentage point productivity adjustment and by 0.3 percentage point; these reductions were mandated by section 3401(g) of ACA.

REGION KEY:

New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; Middle Atlantic=Pennsylvania, New Jersey, New York; South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin; East South Central=Alabama, Kentucky, Mississippi, Tennessee; West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; West South Central=Arkansas, Louisiana, Oklahoma, Texas; Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; Pacific=Alaska, California, Hawaii, Oregon, Washington; Outlying=Guam, Puerto Rico, Virgin Islands

3. Cost Allocation of Quality Reporting

This final rule also implements a hospice patient-level data set to be used by all hospices to collect and submit standardized data about each patient admitted to hospice. This Hospice Item Set will be used to support the standardized collection and calculation of quality measures, collection of the requisite data elements. Hospices will be required to complete and submit an admission HIS and a discharge HIS on all patients admitted to hospice starting July 1, 2014 for FY 2016 APU determination. The admission and discharge HIS will collect the standardized data elements needed to calculate 7 NQF endorsed measures for hospice. The total annualized cost across all hospices, starting July 2014, is estimated to be \$14,287,929. Furthermore, the structural measure related to QAPI indicators and the NQF #0209 pain measure will no longer be required for the hospice quality reporting program beyond data submission for the FY 2015 payment determination. The original intent of the structural measure was for hospices to submit information about number, type, and data source of quality indicators used as a part of their QAPI Program. Data gathered as part of the structural measure were used to ascertain the

breadth and context of existing hospice QAPI programs to inform future measure development activities including the data collection approach for the first year of required reporting (FY 2014). Please refer to section B, the Hospice Quality Reporting Program, for a detailed discussion of these programs.

4. Alternatives Considered

In continuing the reduction to the BNAF by an additional 15 percent, for a total BNAF reduction of 70 percent (10 percent in FY 2010, and 15 percent per year for FY 2011 through FY 2014), and implementing the hospice payment update percentage and the updated wage index. the aggregate impact will be a net increase of \$160 million in payments to hospices. In the proposed rule for FY 2014, we did not consider discontinuing the additional 15 percent reduction to the BNAF as the 7-year phase-out of the BNAF was finalized in the FY 2010 Hospice Wage Index final rule (74 FR 39384). However, if we were to discontinue the reduction to the BNAF by an additional 15 percent, Medicare would pay an estimated \$100 million more to hospices in FY 2014. The final 1.7 percent hospice payment update percentage for FY 2014 is based on a final 2.5 percent inpatient hospital market basket update for FY 2014, reduced by a 0.5 percentage point productivity adjustment and by an additional 0.3 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the market basket percentage for that FY. The Act requires us to use the inpatient hospital market basket to determine the hospice payment rate update. In addition, section 3401(g) of the Affordable Care Act mandates that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage will be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, section 3401(g) of the Affordable Care Act

also mandates that in FY 2013 through FY 2019, the hospice payment update percentage will be reduced by an additional 0.3 percentage point (although for FY 2014 to FY 2019, the potential 0.3 percentage point reduction is subject to suspension under conditions specified in section 1814(i)(1)(C)(v) of the Act). Since the hospice payment update percentage is determined based on statutory requirements, we did not consider not updating hospice payment rates by the payment update percentage.

C. Accounting Statement

As required by OMB Circular A-4 (available at

http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), in Table 12 below, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule. Table 12 provides our best estimate of the increase in FY 2014 Medicare payments under the hospice benefit as a result of the changes presented in this final rule using data for 3,569 hospices in our database. In addition, the table presents the costs to hospice providers for submitting data to the Hospice Item Set starting in July 2014.

TABLE 12-- Accounting Statement: Classification of Estimated Expenditures, From FY 2013 to FY 2014 [in \$Millions]

Transfers		
\$160		
Federal Government to Hospices		
Costs		
\$14.3		
	\$160 Federal Government to Hospices Costs	

^{*}All hospices are required to submit data for the Hospice Item Set starting in July of 2014.

D. Conclusion

In conclusion, the overall effect of this final rule is an estimated \$160 million increase in Federal Medicare payments to hospices due to the wage index changes (including the additional 15 percent reduction in the BNAF) and the final hospice payment update percentage of 1.7 percent. Furthermore, hospices are estimated to incur total costs of \$14.3 million as a result of data submission requirements starting in July 2014. Lastly, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities, or have a significant effect relative to section 1102(b) of the Act.

1. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all hospices are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities by meeting the Small Business Administration (SBA) definition of a small business (in the service sector, having revenues of less than \$7.0 million to \$34.5 million in any 1 year), or being nonprofit organizations. While the SBA does not define a size threshold in terms of annual revenues for hospices, it does define one for home health agencies (\$14 million; see http://www.sba.gov/sites/default/files/files/Size_Standards_Table(1).pdf). For the purposes of this final rule, because the hospice benefit is a home-based benefit, we are applying the SBA definition of "small" for home health agencies to hospices; we will use this definition of "small" in determining if this final rule has a significant impact on a substantial number of small entities (for example, hospices). We estimate that 95 percent of hospices have Medicare revenues below \$14 million or are nonprofit organizations and therefore are considered small entities.

HHS's practice in interpreting the RFA is to consider effects economically "significant" only if they reach a threshold of 3 to 5 percent or more of total revenue or total costs. As noted above, the combined effect of the updated wage data, the additional 15 percent BNAF reduction, and the final FY 2014 hospice payment update percentage of 1.7 percent results in an increase in estimated hospice payments of 1.0 percent for FY 2014. For small and medium hospices (as defined by routine home care days), the estimated effects on revenue when accounting for the updated wage data, the additional 15 percent BNAF reduction, and the final FY 2014 hospice payment update percentage reflect increases in payments of 0.8 percent and 1.0 percent, respectively. Therefore, the Secretary has determined that this final rule will not create a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule only affects hospices. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

2. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately \$141 million. This final rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of \$141 million or

more.

<u>Comment</u>: We received a few comments on Unfunded Mandates Reform Act Analysis section. Commenters disagreed that we did not meet the statutory threshold of the Unfunded Mandates Reform Act of 1995. A commenter stated that the total costs of additional staff time, professional consulting fees and software necessary to comply fully with the new billing; coding, quality reporting and survey administration tasks will exceed that threshold figure of \$141 million.

Response: The hospice benefit covers all care for the terminal prognosis, related conditions, and for the management of pain and symptoms. HIPAA, federal regulations, and the Medicare hospice claims processing manual all require that ICD-9-CM Coding Guidelines be applied to the coding and reporting of diagnoses on hospice claims. In our regulations at 45 CFR 162.1002, the Secretary adopted the ICD-9-CM code set, including The Official ICD-9-CM Guidelines for Coding and Reporting. The CMS' Hospice Claims Processing manual (Pub 100-04, chapter 11) requires that hospice claims include other diagnoses "as required by ICD-9-CM Coding Guidelines." In the proposed rule, we provided guidance from the ICD-9-CM Official Guidelines for Coding and Reporting to highlight coding guidelines for principal and other diagnosis selection, as well as the various coding and sequencing conventions found therein. We are not requiring any new ICD-9-CM coding guidelines in this rule, rather we are reiterating existing policies and reminding providers of the expectations in regards to diagnostic coding on hospice claims. In addition, as indicated in section V of this final rule, we set out the requirements and burden estimates for the Hospice Experience of Care Survey field study and indicated that it is too early to set out the requirements and burden estimates for the national implementation of the survey. We anticipate having the final survey instrument in 2014 and

setting out the collection of information requirements and burden estimates in the proposed rule for CY 2015. In addition, we provided a burden estimate for the Hospice Item Set that providers will be required to submit starting FY 2015, with a total annualized cost across all hospices estimated at \$14,287,929. Therefore, we do not believe that any clarifications or requirements promulgated in this rule exceed the Unfunded Mandates Reform Act threshold.

VII. Federalism Analysis and Regulations Text

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or tribal governments.

List of Subjects in 42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 418 as set forth below:

PART 418—HOSPICE CARE

1. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§418.311 [Amended]

2. Amend § 418.311 by removing the reference to "§ 405.1874" and adding in its place the reference "§ 405.1875".

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: July 24, 2013

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: July 30, 2013

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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